

Megan K. Bannigan (mkbannigan@debevoise.com)
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, New York 10001
(212) 909-6000

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

-----X		
NOVARTIS AG, NOVARTIS	:	Civil Action No. _____
PHARMACEUTICALS CORPORATION,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	COMPLAINT
	:	
NOVADOZ PHARMACEUTICALS LLC, MSN	:	JURY TRIAL DEMANDED
PHARMACEUTICALS INC., MSN	:	
LABORATORIES PRIVATE LIMITED,	:	
	:	
Defendants.	:	
-----X		

Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation (together “Novartis”), by and through their attorneys, Debevoise & Plimpton LLP, bring this action against defendants MSN Laboratories Private Limited (“MSN Labs”), which on information and belief has a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad - 18, Telangana, India, and MSN Pharmaceuticals Inc. (“MSN Pharma”) and Novadoz Pharmaceuticals LLC (“Novadoz Pharma,” and together with MSN Labs and MSN Pharma, “MSN” or “Defendants”), which on information and belief both have a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. In support of this action, Novartis alleges as follows:

INTRODUCTION

1. Novartis brings this lawsuit to protect physicians and patients from being deceived into believing that MSN’s generic version of Novartis’s life-changing drug ENTRESTO® comes from, or is sponsored or authorized by, Novartis based on MSN’s deceptive use of nearly identical trade dresses and the confusingly similar NOVADOZ name.

2. Novartis is a leading pharmaceutical company that is instrumental in helping to save and improve the lives of its patients, including the millions of Americans who suffer from chronic heart failure.

3. ENTRESTO®, a blockbuster drug manufactured by Novartis, is the number one heart failure brand prescribed by physicians. It is a prescription medicine that has helped reduce the risk of death and hospitalization for over 2.5 million patients with chronic heart failure.¹ It helps preserve patients’ quality of life by enhancing their ability to engage in the everyday activities that they find fulfilling but increasingly challenging due to the decreasing function and efficiency of their hearts.

4. Due to the tremendous benefits the drug brings to patients, Novartis has spent significant time and resources building the ENTRESTO® brand and ensuring that patients and their healthcare providers (“HCPs”) are aware of the impact this Novartis drug can have on patients’ wellbeing.

5. Patients and HCPs alike have become intimately familiar with the drug and readily recognize its name, manufacturer, and design—including the distinctive shape, sizes, and

¹ Novartis, Annual Report 2023 II (Jan. 30, 2024), https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2023.pdf (last visited Jan. 26, 2025) (“Other standout performers include Entresto, our treatment for heart failure and hypertension that has now reached more than 2 million patients in the US.”); Entresto, <https://www.entrestohcp.com/> (last visited Jan. 26, 2025) (indication stating: “ENTRESTO is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure”).

colors of the three-tablet regimen for ENTRESTO®. The drug is marketed directly to consumers, and patients who are prescribed ENTRESTO® take it twice per day, indefinitely. Novartis also has heavily marketed the drug to HCPs, who receive physical samples and informational resources featuring images of the drug.

6. MSN now plans to capitalize on Novartis's hard-earned consumer trust and the goodwill associated with the famous NOVARTIS brand and the ENTRESTO® trade dresses by offering a generic version of ENTRESTO® using a scheme designed to confuse HCPs and consumers into believing that MSN's product comes from, or is affiliated with, sponsored by, or authorized by Novartis.

7. On information and belief, MSN's planned generic will do this in two ways. First, although MSN could have selected virtually any shape, size, and color for its tablets, it specifically designed its tablets to be nearly identical to the ENTRESTO® tablets' unique, distinctive, and protectable combinations of shape, size, and color. Second, in a further effort to associate its generic medicine with Novartis, MSN intends to distribute these tablets under its NOVADOZ name—which is likely to confuse physicians and consumers into believing that MSN's generic comes from Novartis and its generics partner Sandoz (which used to be Novartis's wholly owned generics division and continues to be a Novartis partner, even after its sale). MSN's decision to launch this generic drug using the NOVADOZ name, specifically to invoke both **NOVARTIS** and **SANDOZ**, cannot be an accident; rather, it reflects MSN's effort to deceive the marketplace.

8. Novadoz's plan to distribute a generic version of a Novartis branded drug, in a form that looks just like the Novartis branded drug, under the NOVADOZ name, is not only likely to cause consumer confusion, but also likely to cause physical harm to patients based on

key differences between the U.S. Food and Drug Administration (“FDA”) approved labeling and prescribing information for the drugs. In addition, MSN’s scheme is likely to cause reputational and financial harm to Novartis.

9. While Novartis has absolutely no opposition to fair and lawful generic drugs entering the marketplace, it must prevent the harm that will be caused to consumers and the brand through the introduction of generic drugs that are designed specifically to confuse patients and HCPs into believing that the drugs they are respectively taking and prescribing actually are Novartis drugs.

10. Novartis brings this lawsuit for trademark infringement, trade dress infringement, and unfair competition to prevent consumer and reputational harm by stopping Defendants from creating consumer confusion and harming the goodwill of the NOVARTIS trademark and the trade dresses of the ENTRESTO® tablets.

THE PARTIES

11. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

12. Plaintiff Novartis AG is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

13. On information and belief, Defendant MSN Pharma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. On information and belief, MSN Pharma is a wholly owned subsidiary of, and U.S. agent for, MSN Labs.

14. On information and belief, Defendant Novadoz Pharma is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. On information and belief, Novadoz Pharma is a wholly owned subsidiary of, and U.S. agent for, MSN Labs.

15. On information and belief, Defendant MSN Labs is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad -18 , Telangana, India. MSN Labs has admitted to submitting the FDA Abbreviated New Drug Application (“ANDA”) No. 213748 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, (the “MSN Drug”), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the MSN Drug in or into the United States.²

JURISDICTION AND VENUE

16. This Court has original jurisdiction over this action pursuant to 15 U.S.C. § 1121 and 28 U.S.C. §§ 1331, 1338. This Court has supplemental jurisdiction over Plaintiffs’ claims under the common law of the State of New Jersey pursuant to 28 U.S.C. § 1367(a). The Court has jurisdiction over the declaratory judgment count pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

17. This Court has personal jurisdiction over MSN Labs because, on information and belief, it (i) owns MSN Pharma, which has its principal place of business in the State of New Jersey, and Novadoz Pharma, a New Jersey corporation; (ii) manufactures pharmaceuticals at a

² Defendants MSN Laboratories Private Limited, MSN Pharmaceuticals Inc., and MSN Life Sciences Private Limited’s Answer, Affirmative Defenses, and Counterclaims ¶ 34, *Novartis Pharms. Corp. v. MSN Pharms. Inc.*, No. 1:22-cv-01395 (D. Del. Dec. 16, 2022), ECF No. 31.

finished dosage facility in Piscataway, NJ;³ (iii) acted in concert with MSN Pharma to obtain approval from the FDA for the MSN Drug and to bring the MSN Drug to the U.S. market, which is likely to cause confusion among U.S. consumers, including those in the State of New Jersey; and (iv) has transacted business in the State of New Jersey, including by selling pharmaceuticals in New Jersey, either directly or indirectly through its subsidiaries, agents, or affiliates, including MSN Pharma and Novadoz Pharma.

18. This Court has personal jurisdiction over MSN Pharma because its contacts with the State of New Jersey are sufficiently continuous and systematic as to render it at home in this forum, including because, on information and belief, it has a principal place of business in the State of New Jersey and it has transacted business in the State of New Jersey by selling pharmaceuticals in the state, either directly or indirectly through its subsidiaries, agents, or affiliates, including Novadoz Pharma.

19. This Court has personal jurisdiction over Novadoz Pharma because its contacts with the State of New Jersey are sufficiently continuous and systematic as to render it at home in this forum, including because, on information and belief, it is incorporated in the State of New Jersey, it operates its principal place of business in the State of New Jersey, and it has transacted business in the State of New Jersey, including by selling pharmaceuticals in the state.

20. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b)(3) because Plaintiffs are not currently aware of any district in which this action may be brought pursuant to either 28 U.S.C. § 1391(b)(1) or (2), and because Defendants are subject to personal jurisdiction in this District.

³ Decl. of Bharat Reddy Chintapally, Executive Director of MSN, ¶ 4, *Novartis Pharms. Corp. v. MSN Pharms. Inc.*, No. 1:22-cv-01395 (D. Del. Aug. 20, 2024), ECF No. 258.

FACTUAL BACKGROUND

THE FAMOUS NOVARTIS BRAND NAME

21. Novartis AG is one of the world's leading multinational pharmaceutical companies.

22. Formed in 1996 through the merger of two Swiss pharmaceutical companies, Ciba-Geigy AG and Sandoz AG, Novartis has a rich history of innovation rooted not only in its almost three decades of development and manufacture of game-changing medicines and therapies under the Novartis name, but also in centuries of storied innovation through Novartis's two predecessor companies.

23. Building upon this rich history, Novartis is now an innovative medicines company, working to reimagine medicine to improve and extend patients' lives and to empower patients, HCPs, and societies in the face of serious disease.

24. Novartis focuses on four core therapeutic areas—(1) cardiovascular, renal, and metabolic; (2) immunology; (3) neuroscience; and (4) oncology—and its medicines reached more than 284 million people worldwide in 2023 alone.⁴

25. Consistently ranked in the top 10 global pharmaceutical companies, Novartis has become a brand that consumers trust. This is reflected in Novartis's net sales of over \$45.4 billion across 130 countries in 2023,⁵ as well as in the recognition the company has received, including Novartis's inclusion on *Fortune*'s list of the World's Most Admired Companies and Boston Consulting Group's list of the Top 50 Most Innovative Companies.⁶ Novartis was also

⁴ Novartis ranks first in 2024 Access to Medicine Index, Novartis, <https://www.novartis.com/news/media-releases/novartis-ranks-first-2024-access-medicine-index> (last visited Jan. 26, 2025).

⁵ Novartis, Annual Report 2023, at 21, 43.

⁶ Awards and Recognition, Novartis, <https://www.novartis.com/about/awards-and-recognition> (last visited Jan. 26, 2025).

ranked first in the 2024 Access to Medicine Foundation's Index, a ranking of 20 of the world's largest research-based pharmaceutical companies based on their efforts to improve access to medicines, vaccines, and diagnostics in low- and middle-income countries.⁷

26. To help ensure that consumers receive the high-quality medicines they have come to expect from Novartis, Novartis invests in, and stringently protects, its now famous trademark (the "NOVARTIS Trademark") and uses that mark as a consistent designator of source across Novartis's products.

27. As part of those efforts, Novartis has consistently used the NOVARTIS Trademark on the packaging and inserts for each of its medications, as shown below.



[CONTINUED ON NEXT PAGE]

⁷ 2024 Access to Medicine Index, Access to Medicine Foundation, <https://accesstomedicinefoundation.org/sectors-and-research/index-ranking> (last visited Jan. 26, 2025).



28. Novartis has spent billions of dollars to market its drugs, under the NOVARTIS Trademark, in the United States—a top market for Novartis, where the company operates through Novartis Pharmaceuticals Corporation, a subsidiary of Novartis AG, headquartered in East Hanover, New Jersey.

29. Using the NOVARTIS Trademark, Novartis advertises its pharmaceuticals to the general U.S. public via digital and traditional media channels, including the internet, television, newspapers, and magazines. In each of these forums, the NOVARTIS Trademark is prominently featured, ensuring that the public recognizes Novartis as the source of the advertised treatments.

30. Some of Novartis's most well-known marketing efforts feature celebrity patients who benefit from Novartis's medications. For example, Novartis has worked with Grammy award-winning singer Cyndi Lauper for nearly a decade to promote COSENTYX®, a Novartis

medication to treat plaque psoriasis.⁸ Nationally broadcast television spots featuring Ms. Lauper include the NOVARTIS Trademark, along with that of COSENTYX®:



9

31. Similarly, to promote KESIMPTA®, a Novartis medication used to treat multiple sclerosis, Novartis partnered with actress Jamie-Lynn Sigler, from the television show *The Sopranos*, who has mentioned her work with Novartis in *People* magazine,¹⁰ and has been featured in television ads that include the NOVARTIS Trademark:

⁸ See Andrea Park, *Novartis standbys Cyndi Lauper, Michelle Bernstein unite to report Cosentyx is 'Still Working'*, Fierce Pharma (May 17, 2024, 4:26 PM), <https://www.fiercepharma.com/marketing/novartis-standbys-cyndi-lauper-michelle-bernstein-unite-report-cosentyx-still-working> (last visited Jan. 26, 2025).

⁹ See COSENTYX TV Spot, “Years” Featuring Cyndi Lauper, iSpot.tv, <https://www.ispot.tv/ad/o9Um/cosentyx-years-featuring-cyndi-lauper> (aired Oct. 29, 2019) (last visited Jan. 26, 2025); see also COSENTYX TV Spot, “See Me” Featuring Cyndi Lauper, iSpot.tv, <https://www.ispot.tv/ad/o9c7/cosentyx-see-me-featuring-cyndi-lauper> (aired Oct. 29, 2019) (last visited Jan. 26, 2025).

¹⁰ Julie Jordan, *Jamie-Lynn Sigler Says She’s ‘Living a Very Full Life’ Despite Relapsing Multiple Sclerosis (Exclusive)*, *People* (Nov. 15, 2023, 10:00 AM), <https://people.com/jamie-lynn-sigler-living-a-very-full-life-despite-relapsing-ms-exclusive-8391714> (last visited Jan. 26, 2025) (“[Sigler is] now determined to help others affected by MS with a three-step process she created with the pharmaceutical company Novartis, for which she is a spokesperson: acceptance of the disease, reframing reality and asking for help.”).



32. Based on these extensive promotional efforts (and particularly its consumer-focused advertising), in 2024, Novartis won “Integrated Campaign of the Year” in the “Healthcare Marketing Impact Awards” for its use of testimonials and digital touchpoints.¹²

33. In addition, Novartis (along with its famous NOVARTIS Trademark) has been featured in major news publications including *The New York Times*,¹³ *The Wall Street Journal*,¹⁴

¹¹ KESIMPTA TV Spot, “My Time” Featuring Jamie-Lynn Sigler, iSpot.tv, <https://www.ispot.tv/ad/5C85/kesimpta-my-time-featuring-jamie-lynn-sigler> (aired Nov. 13, 2023) (last visited Jan. 26, 2025).

¹² Asa Hiken, *Novartis shines a light on skin disease using testimonials and digital touchpoints*, AdAge (Nov. 12, 2024), <https://adage.com/article/special-report-healthcare-marketing-impact-awards/novartis-healthcare-marketing-impact-awards-2024/2585176> (last visited Jan. 26, 2025).

¹³ Associated Press, *Novartis to Buy the Medicines Company for 9.7 Billion*, The New York Times (Nov. 24, 2019), <https://www.nytimes.com/2019/11/24/business/novartis-medicines-company-cholesterol.html> (last visited Jan. 26, 2025).

¹⁴ Helena Smolak, *Novartis Raises Profit Guidance as Key Drugs Boost Sales*, The Wall Street Journal (Jul. 18, 2024), <https://www.wsj.com/business/earnings/novartis-raises-profit-guidance-as-key-drugs-boost-sales-d6a79f0e> (last visited Jan. 26, 2025); Jared S. Hopkins, *How Novartis’s CEO Learned From Mistakes and Got Help From an Unlikely Quarter*, The Wall Street Journal (Sept. 3, 2023), <https://www.wsj.com/health/pharma/how-novartiss-ceo-learned-from-his-mistakes-and-got-help-from-an-unlikely-quarter-b087ebbb> (last visited Jan. 26, 2025).

and *The Washington Post*,¹⁵ all of which have substantial readerships throughout the United States.

34. Novartis further maintains an active presence on social media websites, where it uses the NOVARTIS Trademark on posts and content designed to inform investors, patients, and HCPs about the company's mission and developments in its research. Across YouTube, Facebook, X, and Instagram, Plaintiffs' Novartis-branded accounts have approximately 886,300 followers.¹⁶

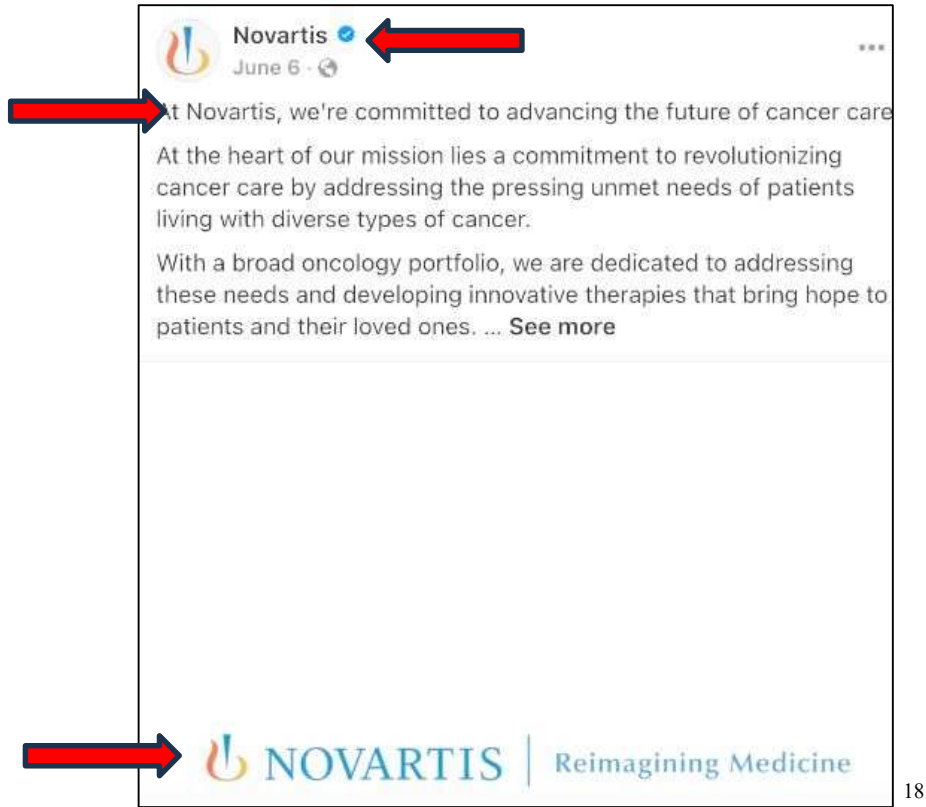
35. Social media posts on these accounts consistently feature the NOVARTIS Trademark, further cultivating the prominence and renown of the Novartis brand.



¹⁵ Carolyn Y. Johnson, *Major drug study opens up vast new opportunities in combating heart disease*, *The Washington Post* (Aug. 27, 2017), <https://www.washingtonpost.com/news/wonk/wp/2017/08/27/major-drug-study-opens-up-vast-new-opportunities-in-combating-heart-disease/> (last visited Jan. 26, 2025).

¹⁶ YouTube (38.2K subscribers); Facebook (431K followers); X (296.1K followers), and Instagram (121K followers).

¹⁷ Novartis Facebook Post (Apr. 15, 2024), <https://fb.watch/vRasE8RD6v/> (last visited Jan. 26, 2025).



36. Novartis takes additional steps to ensure that HCPs are familiar with the Novartis brand. Trained Novartis sales representatives meet with tens of thousands of physicians, pharmacists, hospitals, insurance groups, managed care organizations, and other HCPs every year to educate them on the therapeutic benefits and risks of Novartis's products.

37. Novartis also hosts branded booths at leading medical conferences, like the one shown on the next page, to raise its overall brand recognition in the healthcare field.

¹⁸ Novartis Facebook Post (Jun. 6, 2024), <https://fb.watch/vRaq1Mn6K4/> (last visited Jan. 26, 2025).



38. Within the United States, Novartis's marketing efforts have made the NOVARTIS Trademark widely recognized among those working in the healthcare industry, as well as the general public.

39. This widespread recognition of the NOVARTIS Trademark is reflected in Novartis's net sales figures from the last five years in the United States, which have consistently amounted to billions of dollars and steadily increased over time (as shown in the table below).

2019	2020	2021	2022	2023
\$ 13,788,602,008	\$ 14,341,884,333	\$ 14,999,403,427	\$ 15,899,367,710	\$ 18,096,469,184

40. Novartis not only has cultivated undeniably strong rights in its famous NOVARTIS Trademark through use in commerce, but also owns five incontestable United States trademark registrations for the standard character NOVARTIS mark (Registration Nos.

¹⁹ Angus Liu, *Radiotherapy leader Novartis brings US isotope production in house, builds West Coast plant*, Fierce Pharma (Sept. 4, 2024, 11:24 AM), <https://www.fiercepharma.com/manufacturing/novartis-erects-3rd-radiotherapy-facility-us-brings-isotope-production-house-amid> (last visited Jan. 26, 2025).

4,986,124; 2,336,960; 2,997,235; 5,420,583; 6,841,619). These registrations cover, among other things, pharmaceutical preparations to treat a range of health conditions, scientific research and analysis, and the provision of health care information (collectively, the “NOVARTIS Registered Trademarks,” which, together with Novartis’s common law rights comprise the Novartis Trademark defined in Paragraph 26).

NOVARTIS’S RELATIONSHIP WITH SANDOZ

41. From 2003 to 2023, Sandoz was the name of Novartis’s generics and biosimilars division. The name Sandoz was chosen because it was the name of one of Novartis’s predecessor companies—Sandoz AG, a company with over 100 years of experience in developing innovative products before its merger with Ciba-Geigy AG in 1996 to create Novartis.

42. During the 20 years that Sandoz was a division of Novartis, it was one of the largest generic drug makers in the world by revenue.

43. Sandoz’s consistent use of the NOVARTIS Trademark created a persisting link between Sandoz and Novartis in the minds of consumers.

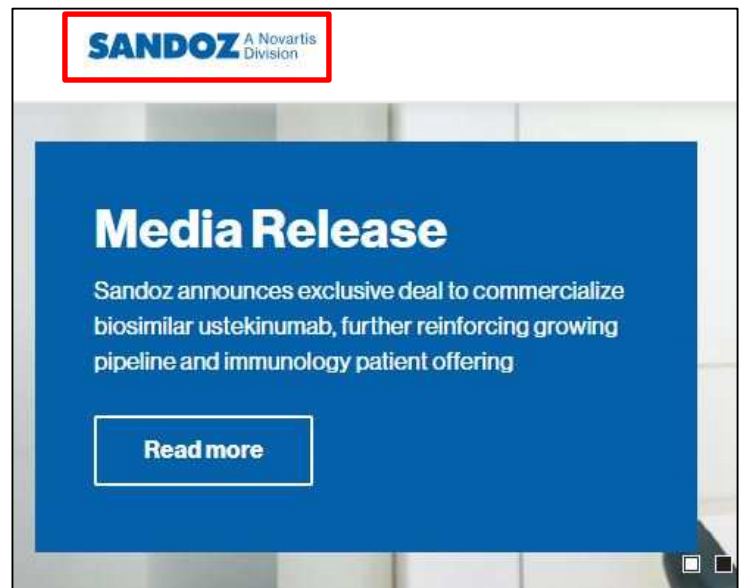
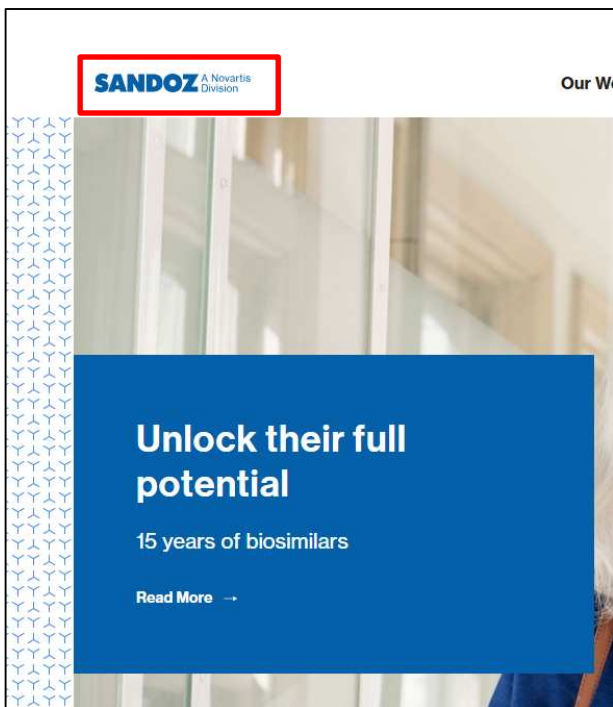
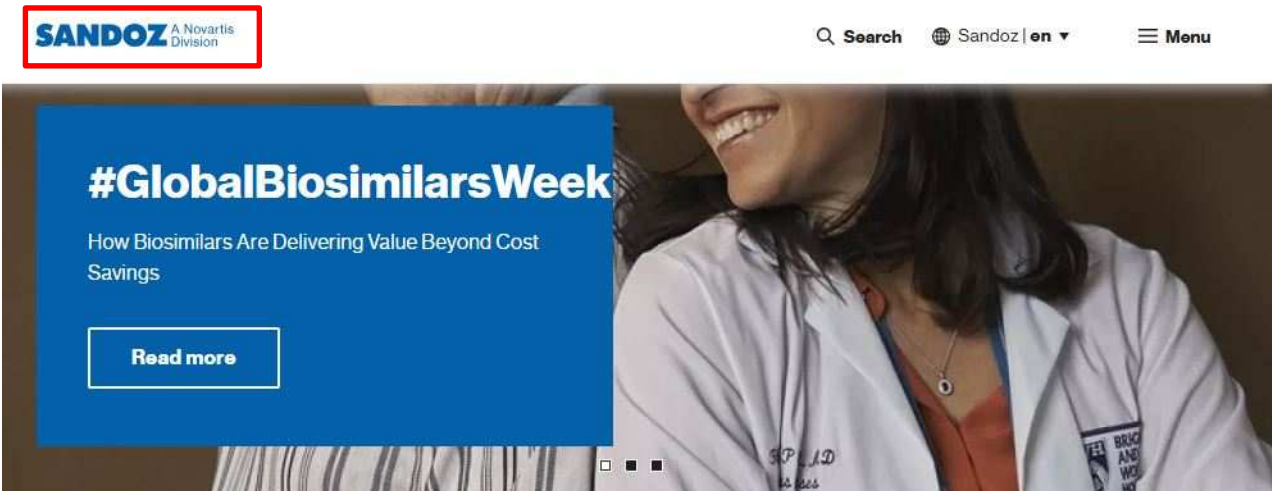
44. For example, from approximately 2013 through 2023, Sandoz consistently identified itself as a “Novartis Division” or a “Novartis Company” on its product containers and inserts, as shown on the next page.

[CONTINUED ON NEXT PAGE]

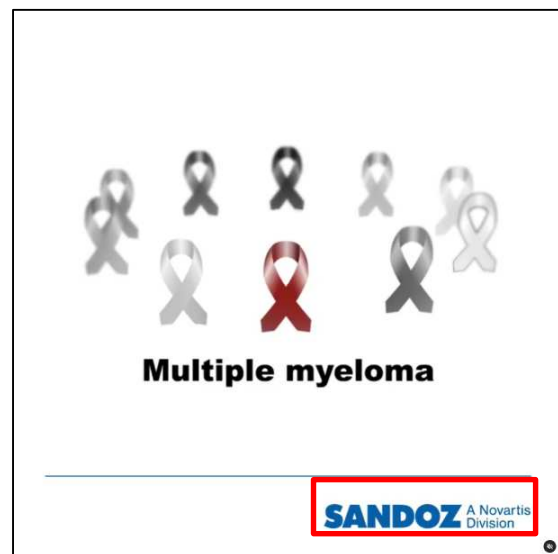


45. The SANDOZ and NOVARTIS marks were also used together in marketing materials directed at patients and HCPs, including the Sandoz website, which identified the company as a “Novartis Division” at the top of each sub-page of the website, including the homepage depicted on the next page.

[CONTINUED ON NEXT PAGE]



46. Sandoz further used the NOVARTIS Trademark in posts on its social media pages.





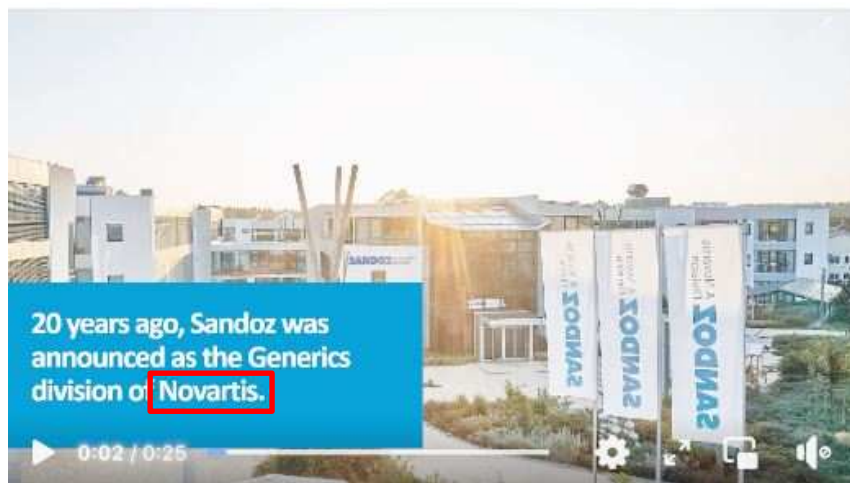
Sandoz Global

January 21, 2023 · 🌐



20 years ago, Sandoz was announced as the Generics division of **Novartis**. Since then, we have made great strides towards our ambition to become the leading and most valued generics company.

At Sandoz we're committed to playing a key role in achieving global healthcare goals. Today we are a global leader in generic pharmaceuticals and biosimilar medicines. As we prepare to potentially become a standalone company, our goal remains to serve patients by improving access to affor... [See more](#)



47. At industry events and conferences, Sandoz made its affiliation with Novartis clear through use of the NOVARTIS Trademark on its booths and displays.



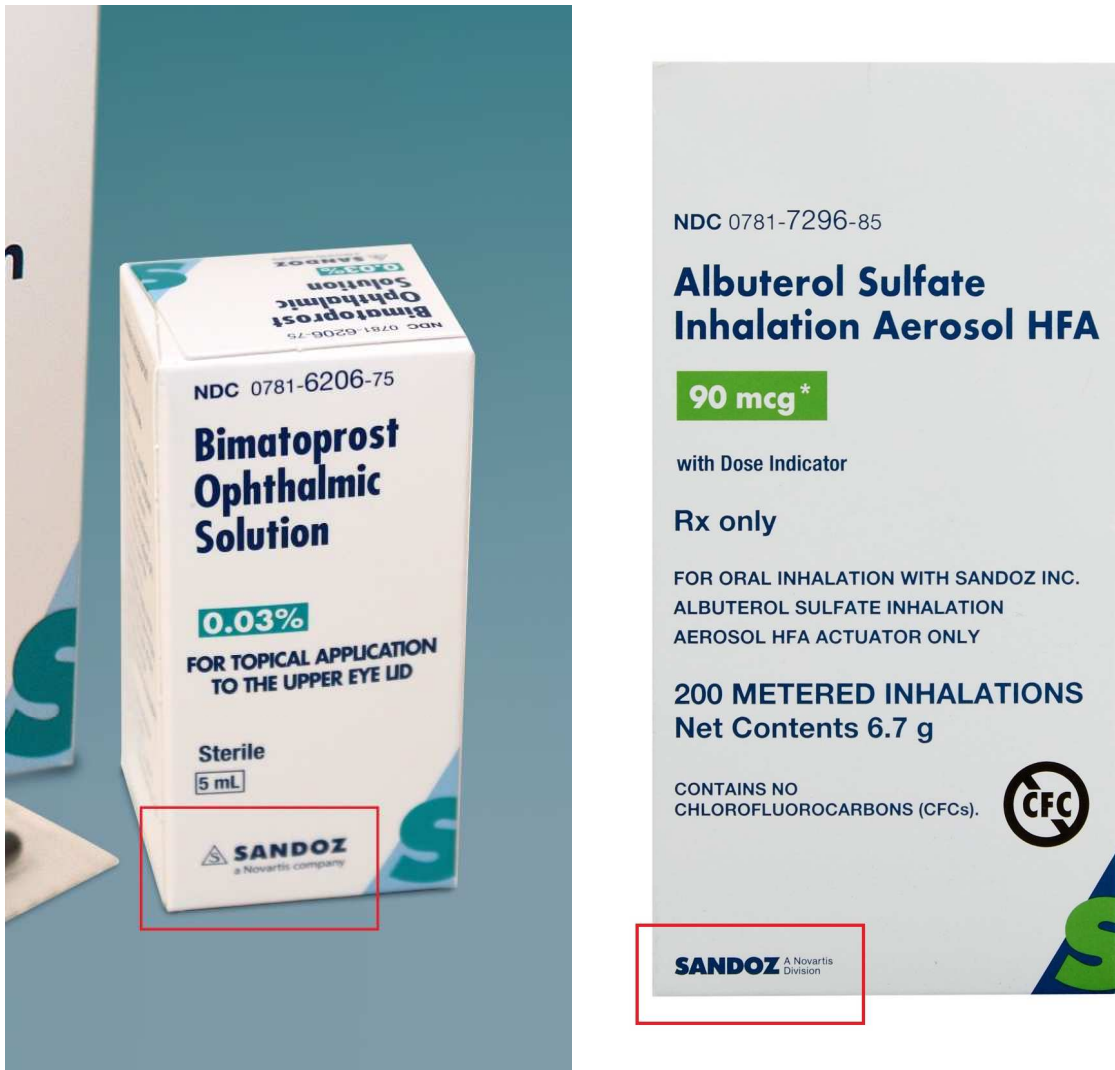


48. At these events, Novartis also advertised Sandoz as part of its corporate family, in conjunction with its NOVARTIS Trademark.



49. While Sandoz was spun off from Novartis and became an independent company in October 2023, Sandoz continues to use the NOVARTIS Trademark today.

50. Sandoz and Novartis have a reciprocal license to transition away from co-branded uses of their respective SANDOZ and NOVARTIS marks on materials that existed prior to the separation of the two companies, including drug labels. As a result, the NOVARTIS Trademark can still be found on Sandoz medications for sale. For example:



20

²⁰ Albuterol Sulfate 90 mcg Aerosol 6.7 Gram 200 Doses, McKesson, <https://mms.mckesson.com/product/1194739/Sandoz-00781729685> (last visited Jan. 26, 2025); Bimatoprost

51. Based on these continuing joint uses of the SANDOZ and NOVARTIS trademarks and the many years of co-branding by the companies, HCPs and consumers of generic medications perceive Novartis as integrally tied to both Sandoz and the generics market. After decades of Novartis's co-branding with Sandoz, consumers derive comfort from and exhibit an enhanced willingness to rely upon generic products associated with the NOVARTIS Trademark.

SUCCESS OF ENTRESTO®

52. ENTRESTO® is a Novartis prescription medicine that is approved by the FDA to reduce the risk of death and hospitalization in adult patients with chronic heart failure.

53. Since launching in 2015, ENTRESTO® has been the only tablet that combines the active ingredients sacubitril and valsartan. These ingredients help patients suffering from chronic heart failure by improving the heart's ability to pump blood to the body.

54. Chronic heart failure is a very serious condition that can lead to many complications and even death. A heart's failure to pump blood efficiently can deprive organs of vital oxygen and nutrients; lead to fluid buildup that puts pressure on, and impairs the function of, the liver; and can weaken the heart muscle, increasing the risk of sudden cardiac death.

55. In addition, the often very apparent, daily symptoms of chronic heart failure include conditions like fatigue, shortness of breath, and fluid retention that make everyday life difficult.

56. At a high level, ENTRESTO® helps to treat these symptoms by enhancing the effectiveness of beneficial proteins and blocking harmful hormones to help reduce sodium

0.03% Solution 5 mL, <https://mms.mckesson.com/product/1046390/Sandoz-00781620675> (last visited Jan. 26, 2025).

retention and dilate the blood vessels, making it easier for the heart to pump blood through the body.

57. Patients taking ENTRESTO® experience improved quality of life and fewer heart failure exacerbations requiring hospitalization.

58. Today, ENTRESTO® is the number one branded treatment for heart failure prescribed by cardiologists. Novartis estimates that ENTRESTO® has helped over 2.5 million people with heart failure in the United States.²¹

ENTRESTO®'S MULTI-COLORED TABLETS ARE SOURCE-IDENTIFYING

59. ENTRESTO® is offered in three doses.²² Each dose is offered in a unique combination of size, shape, and color. The 24/26 mg dose is a violet white oval tablet, measuring 13.1 mm x 5.2 mm (the “Low Starting Dose Trade Dress”); the 49/51 mg dose is a pale yellow oval tablet, measuring and 13.1 mm x 5.2 mm (the “Recommended Starting Dose Trade Dress”); and the 97/103 mg dose is a light pink oval tablet, measuring 15.1 mm x 6.0 mm (the “Target Dose Trade Dress”).²³ Together, the look and feel of this trio of tablets constitute the ENTRESTO® trade dress (the “Trio Trade Dress” and, together with the Low Starting Dose Trade Dress, Recommended Starting Dose Trade Dress, and Target Dose Trade Dress, the “ENTRESTO® Trade Dresses”).

²¹ Novartis, Annual Report 2023, at II, 44.

²² Novartis also offers the ENTRESTO® SPRINKLE, which is not part of this proceeding. The ENTRESTO® SPRINKLE consists of sacubitril and valsartan oral tablets within a capsule that can be mixed with food for ease of administration in, for example, pediatric patients. See ENTRESTO® SPRINKLE prescribing information, https://www.entrestohcp.com/sites/entrestohcp_com/files/documents/entresto.pdf#page=25 (last visited Jan. 26, 2025).

²³ See Center for Drug Evaluation and Research Application Number 207620Orig1s000, Chemistry Review 6 (June 30, 2015), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/207620Orig1s000ChemR.pdf (last visited Jan. 26, 2025) (identifying color, shape, and size of ENTRESTO® tablets).



60. Patients generally start their course of treatment by taking one of the starting doses for two to four weeks. Over time, many patients progress from the lower doses to the final, target dose (the highest dose). Through this progression, some patients are exposed to the trio of tablets—the Trio Trade Dress.

61. While taking ENTRESTO® (no matter the dose), the tablets become part of a patient's daily routine—ENTRESTO® is a twice-daily-medication that is taken indefinitely to maintain its benefits. This means that patients consistently interact with at least one of the ENTRESTO® Trade Dresses two times a day, every single day.

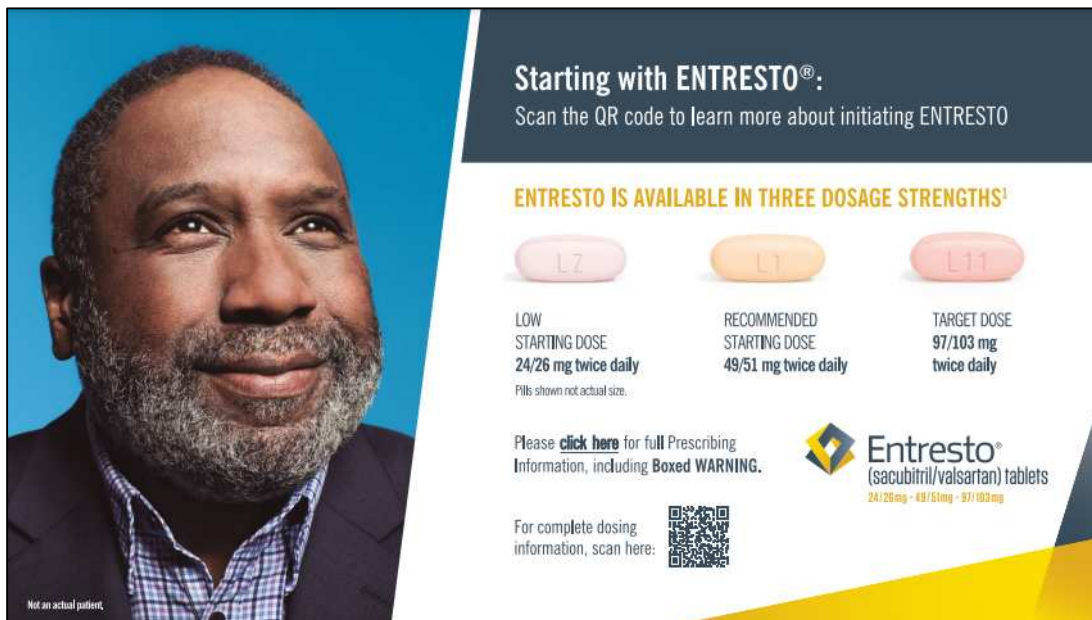
62. It is only natural that the millions of patients who take ENTRESTO® twice a day, every day, have come to identify the look and feel of the ENTRESTO® tablets—particularly their size, color, and shape—as source identifying and an indication of the high quality that patients struggling to manage their daily health deserve.

63. Beyond patients' exposure to the ENTRESTO® Trade Dresses through extensive interaction with the physical tablets, substantial advertising spend and promotional efforts featuring the ENTRESTO® Trade Dresses, sales interactions with HCPs, third-party recognition featuring the ENTRESTO® Trade Dresses, and significant sales of ENTRESTO® further support that each of the ENTRESTO® Trade Dresses has acquired secondary meaning and serves as an identifier of source amongst not only patients but also HCPs.

64. Novartis has spent millions of dollars developing U.S. promotions of ENTRESTO® featuring the Trade Dresses.

65. The materials that Novartis distributes to physicians, hospitals, and other HCPs consistently highlight the ENTRESTO® Trade Dresses when introducing HCPs to the drug's three doses and explaining how to add the drug to a patient's care plan.

66. For example, Novartis includes images of the ENTRESTO® Trade Dresses on the front of a “Dosing Flash Card” that it gives physicians:²⁴



67. The same image of the ENTRESTO® Trade Dresses is included in ENTRESTO®’s “Initiation Guide for Providers”:²⁵

²⁴ HCP Dosing Flash Card, Entresto, https://www.entrestohcp.com/sites/entrestohcp_com/files/documents/hcp-dosing-flashcard.pdf (last visited Jan. 26, 2025).

²⁵ Initiation Guide for Providers, Entresto, https://www.entrestohcp.com/sites/entrestohcp_com/files/documents/entresto-initiation-guide-for-providers.pdf (last visited Jan. 26, 2025).

Start ENTRESTO® with confidence

HOW TO PRESCRIBE ENTRESTO TO YOUR ADULT PATIENTS⁷
Choose initial dose of ENTRESTO, and after 2 to 4 weeks, titrate to the target dose, as tolerated by the patient.

ENTRESTO IS AVAILABLE IN 3 DOSAGE STRENGTHS⁷:

 Low Starting Dose 24/26 mg BID	 Recommended Starting Dose 49/51 mg BID	 Target Dose 97/103 mg BID
---	---	--

Pills shown not actual size.

When switching from an ACEi, be sure to allow for a 1.5-day washout period prior to initiating ENTRESTO⁷

When switching from an ARB, start ENTRESTO at your patients' next scheduled dose⁷

- ENTRESTO is contraindicated with concomitant use of an ACE inhibitor and in patients with a history of angioedema related to previous ACE inhibitor or ARB therapy
- Avoid use of ENTRESTO with an ARB, because ENTRESTO contains the angiotensin II receptor blocker valsartan

Not actual patients.



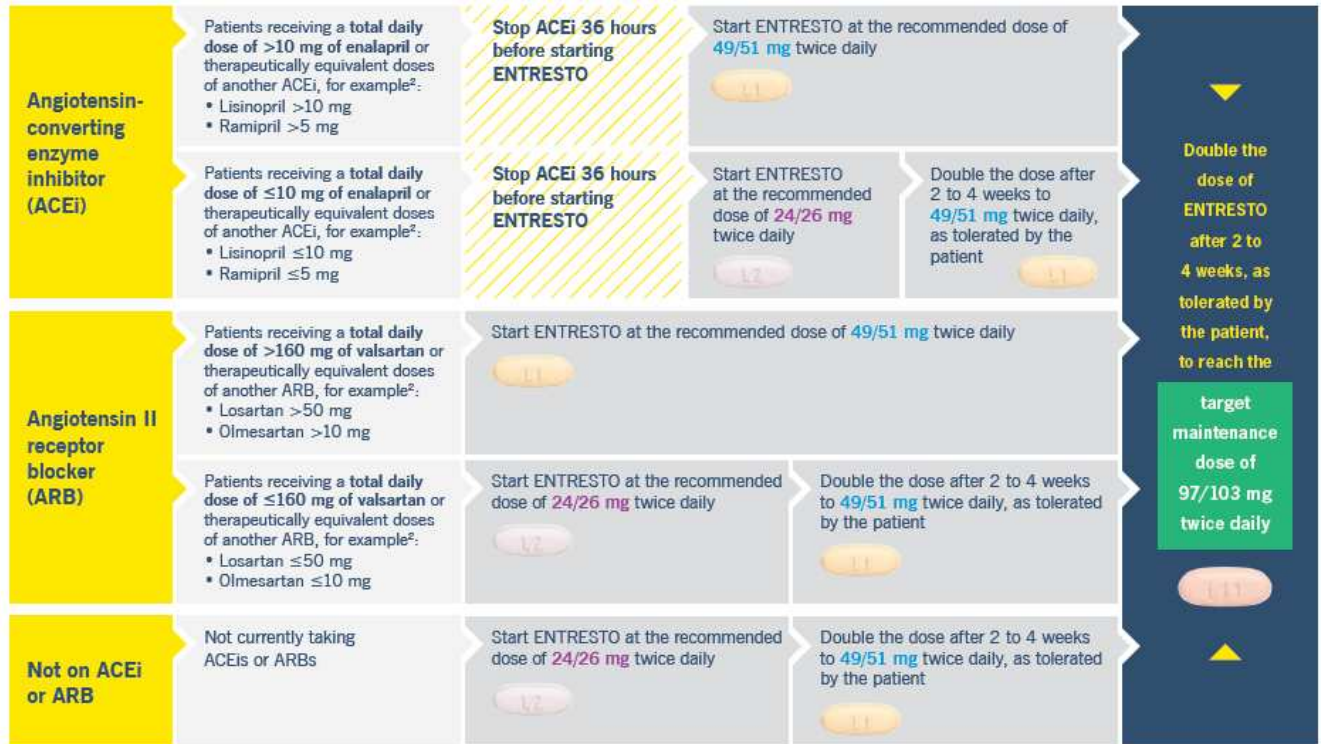
68. Likewise, the website dedicated to educating HCPs on how to prescribe ENTRESTO® includes an educational video about the patient journey that shows the ENTRESTO® Trade Dresses, as well as a webpage that features the ENTRESTO® Trade Dresses:²⁶



The screenshot shows the ENTRESTO HCP website. The header includes navigation links for Patients, HCP, and a note that the site is for US Health Care Professionals only. The main content area is titled "Start ENTRESTO® with confidence" and states that ENTRESTO film-coated tablets are available in 3 dosage strengths¹. It displays three pill images with their respective dosages: Low Starting Dose (24/26 mg BID), Recommended Starting Dose (49/51 mg BID), and Target Dose (97/103 mg BID). Below the pills, it says "Pills shown not actual size." The section "How to prescribe ENTRESTO to your adult patients" advises choosing the initial dose based on current treatment and titrating to the target dose¹. A sidebar on the left contains links to Home, About Heart Failure, Clinical Guideline and Consensus Pathway, HFpEF, HFpEF with LVEF ≤50%, and Safety & Compliance.

69. Novartis has included images of the ENTRESTO® Trade Dresses in materials it distributes to HCPs since the drug's launch in 2015. For example, images of the ENTRESTO® Trade Dresses appear on a 2015 "Dosing and Titration Guide" Novartis distributed to physicians:

²⁶ Dosing, Entresto, <https://www.entrestohcp.com/safety-and-dosing/dosing> (last visited Jan. 26, 2025).




70. Novartis has further distributed \$29.8 million in samples to physicians to give to their patients, helping to ensure that physicians see, and are familiar with, the ENTRESTO® Trade Dresses.

71. Novartis's efforts to market the benefits of ENTRESTO® have made the shape, colors, and sizes of the trio of tablets well-known among HCPs who work with patients facing chronic heart failure.


72. Novartis provides materials that include the ENTRESTO® Trade Dresses to physicians to distribute to their patients. For example, a page in an in-office brochure:

HOW TO TAKE ENTRESTO


Take your dose of ENTRESTO twice daily, exactly as prescribed. Your doctor will decide which dose is right for you.



24/26 mg



49/51 mg



97/103 mg

Pills shown not actual size.

Take ENTRESTO with or without food.
Take ENTRESTO at the same time each day to help you avoid missing a dose.


HOW ENTRESTO WORKS/DOSING

If you have been prescribed ENTRESTO and are currently taking an ACE inhibitor*:



STOP

**Stop taking your
ACE
inhibitor***



WAIT

**Wait for
36
hours**



GO

**Start taking
ENTRESTO,
as prescribed**

*Such as enalapril or lisinopril.

IMPORTANT SAFETY INFORMATION

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take potassium supplements or a salt substitute; nonsteroidal anti-inflammatory drugs (NSAIDs); lithium; or other medicines for high blood pressure or heart problems such as an ACE inhibitor, ARB, or aliskiren.

5

73. And a Heading Home Digital Kit that offers a “quick guide for patients that are heading home with ENTRESTO®,”²⁷ depicted on the next page.

²⁷ Support & Resources, Entresto, <https://www.entrestohcp.com/support-and-resources/patient-resources> (last visited Jan. 26, 2025).

HOW TO TAKE ENTRESTO®

ENTRESTO is a twice-daily medicine. You should take your dose of ENTRESTO exactly as prescribed by your doctor. ENTRESTO is usually given with other Heart Failure medicines in place of an ACE inhibitor or other ARB. **Take ENTRESTO every day as prescribed. If you stop taking ENTRESTO, the medicine will stop working for you.**

ENTRESTO is a tablet that comes in the following doses:



24/26 mg



49/51 mg



97/103 mg

If you have been prescribed ENTRESTO and are currently taking an ACE inhibitor*:



STOP

Stop taking your
ACE
inhibitor*



WAIT

Wait for
36
hours



GO

Start taking
ENTRESTO,
as prescribed

*Such as enalapril or lisinopril.

IMPORTANT SAFETY INFORMATION (cont)

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you take potassium supplements or a salt substitute; nonsteroidal anti-inflammatory drugs (NSAIDs); lithium; or other medicines for high blood pressure or heart problems such as an ACE inhibitor, ARB, or aliskiren.

Do not take ENTRESTO if you:

- are allergic to any of the ingredients in ENTRESTO
- have had an allergic reaction including swelling of your face, lips, tongue, throat (angioedema), or trouble breathing while taking a type of medicine called an angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB)

See additional Important Safety Information throughout and on page 5. Please [click here](#) for full Prescribing Information.



Entresto®
(sacubitril/valsartan) tablets
24/26mg • 49/51mg • 97/103mg

2

74. Novartis also markets directly to patients using direct-to-consumer advertising that educates patients, including those in the United States, on the potential benefits of ENTRESTO®.

75. Showing patients images of the ENTRESTO® Trade Dresses is central to these efforts. For example, Novartis has a patient-focused website where it provides information to consumers hoping to learn more about ENTRESTO®, as well as existing patients looking for

additional information about the medication. This website includes images of the ENTRESTO® Trade Dresses, much like the physician-facing webpage.²⁸

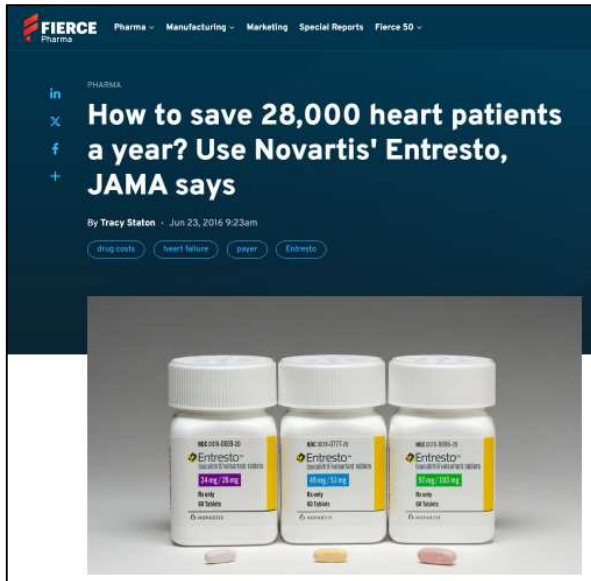
76. Press coverage of ENTRESTO® has further introduced the public to the look and feel of the ENTRESTO® tablets, adding to the association of ENTRESTO® with the size, shape, and color of the low, recommended, and target dose ENTRESTO® tablets. In addition to featuring images of the ENTRESTO® tablets, this press coverage features the NOVARTIS Trademark and highlights the pills as Novartis's ENTRESTO®. For example:



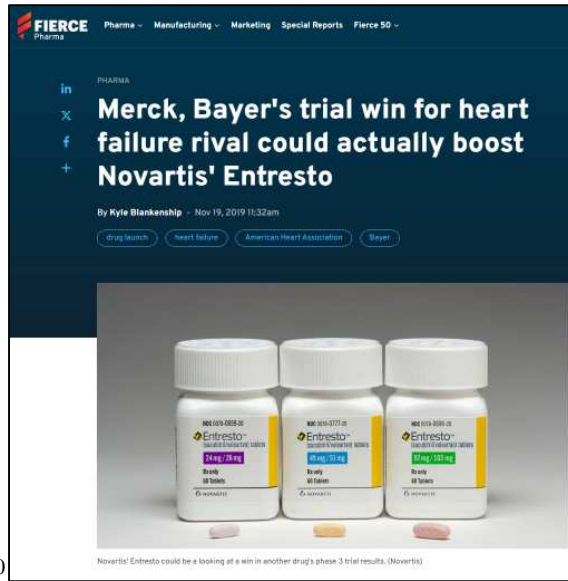
29

²⁸ Starting Entresto, Entresto, <https://www.entresto.com/starting-entresto> (last visited Jan. 26, 2025).

²⁹ *Novartis reports positive new heart failure data for Entresto*, the Financial (Apr. 5, 2018), <https://finchannel.com/novartis-reports-positive-new-heart-failure-data-for-entresto/72712/business-2/pharmacy/2018/04/> (last visited Jan. 26, 2025).



30

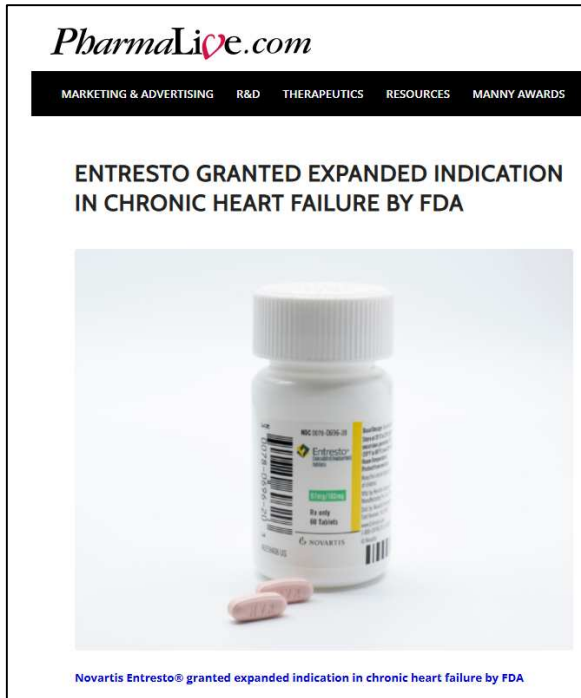


31



32

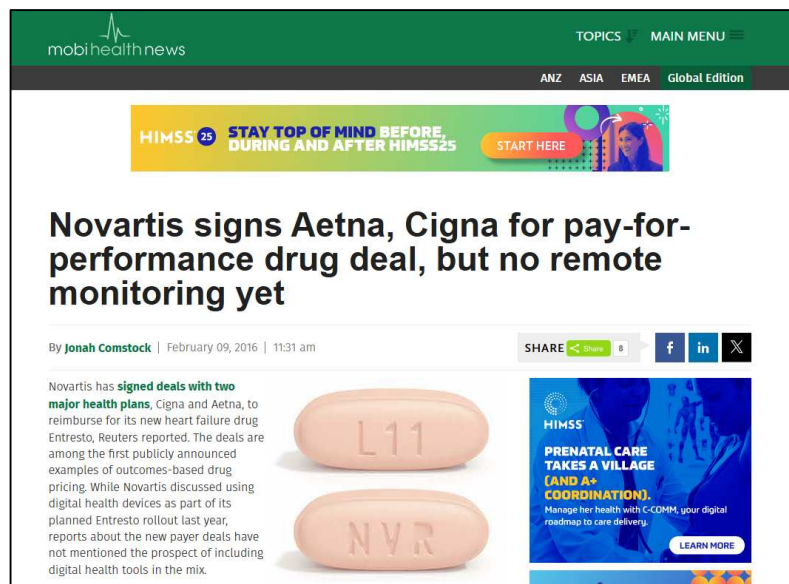
- ³⁰ Tracy Staton, *How to save 28,000 heart patients a year? Use Novartis' Entresto, JAMA says*, Fierce Pharma (June 23, 2016, 9:23 AM), <https://www.fiercepharma.com/pharma/how-to-save-28-000-heart-patients-a-year-use-novartis-entresto-jama-says> (last visited Jan. 26, 2025).
- ³¹ Kyle Blankenship, *Merck, Bayer's trial win for heart failure rival could actually boost Novartis' Entresto*, Fierce Pharma (Nov. 19, 2019, 11:32 AM), <https://www.fiercepharma.com/pharma/merck-bayer-drug-s-trial-win-for-entresto-competitor-could-actually-be-a-boon-for-novartis> (last visited Jan. 26, 2025).
- ³² Angus Liu, *FDA reviewers argue for Novartis ahead of Entresto advisory panel confab*, Fierce Pharma (Dec. 11, 2020, 12:29 PM), <https://www.fiercepharma.com/marketing/where-do-you-stand-fda-reviewers-argue-for-novartis-entresto-committee-meeting-file> (last visited Jan. 26, 2025).



33



34



35

- ³³ Andrew Humphreys, *ENTRESTO GRANTED EXPANDED INDICATION IN CHRONIC HEART FAILURE BY FDA*, PharmaLive.com (Feb. 16, 2021), <https://www.pharmalive.com/entresto-granted-expanded-indication-in-chronic-heart-failure-by-fda/> (last visited Jan. 26, 2025).
- ³⁴ Virginia Lau, *Novartis says slow Entresto sales due to limited access*, MM+M (Jan. 28, 2016, 3:30 PM), <https://www.mmm-online.com/home/channel/payers-managed-markets/novartis-says-slow-entresto-sales-due-to-limited-access/> (last visited Jan. 26, 2025).
- ³⁵ Jonah Comstock, *Novartis signs Aetna, Cigna for pay-for-performance drug deal, but no remote monitoring yet*, Mobi Health News (Feb. 9, 2016, 11:31 AM), <https://www.mobihealthnews.com/content/novartis-signs-aetna-cigna-pay-performance-drug-deal-no-remote-monitoring-yet>. (last visited Jan. 26, 2025).



36



37

77. The distinctiveness of the ENTRESTO® Trade Dresses is also reflected through substantial sales volumes.

78. ENTRESTO® is one of Novartis's best-selling pharmaceuticals, with more than \$10.5 billion in cumulative net sales in the United States between 2015 and 2023. In 2021, ENTRESTO® generated \$1.7 billion in sales in the United States. In 2022, that figure grew to approximately \$2.4 billion. In 2023, it totaled over \$3 billion, accounting for a substantial share of Novartis's revenue.

79. Sales of ENTRESTO® are expected to have exceeded \$3.5 billion in 2024 due to Novartis's efforts to educate patients and HCPs about the drug's life-changing capabilities as well as market dynamics in the United States, such as an aging population and the rising incidence rate of health conditions that contribute to heart failure.

³⁶ *Sacubitril/Valsartan Does Not Outperform ACE Inhibitor in Preventing Heart Failure After Heart Attack*, DAIC (May 15, 2021), <https://www.dicardiology.com/content/sacubitrilvalsartan-does-not-outperform-ace-inhibitor-preventing-heart-failure-after-heart> (last visited Jan. 26, 2025).

³⁷ Bob Herman, *Insurers, drugmakers wrestle with how to build value-based contracts*, Modern Healthcare (Feb. 19, 2016, 11:00 PM), <https://www.modernhealthcare.com/article/20160220/MAGAZINE/302209963/insurers-drugmakers-wrestle-with-how-to-build-value-based-contracts> (last visited Jan. 26, 2025).

80. Consumers also link ENTRESTO® with the stellar reputation of Novartis.

81. Consumers and physicians know they can trust Novartis to provide high quality cardiovascular treatments. According to a 2024 consumer perception survey released by ZoomRx, Novartis was the top-ranking pharmaceutical company developing heart-disease-focused drugs. The study surveyed clinicians and asked them to rank pharmaceutical companies based on metrics including promotion efforts, patient centricity, healthcare provider centricity, innovation, and reputation. Doctors surveyed noted Novartis's "patient commitment and engagement," and specifically called out ENTRESTO® as a "key reputation driver."³⁸

THE ENTRESTO® TRADE DRESSES SERVE NO FUNCTIONAL PURPOSE

82. There is an "increasingly competitive group of branded therapies in heart failure."³⁹

83. For example, Merck & Co. and Bayer launched VERQUVO®, a competitor to ENTRESTO®, in 2021, shortly after AstraZeneca's FARXIGA® also entered the heart failure medication market.⁴⁰

84. As shown on the next page, the tablets made by these and other third-party pharmaceutical companies to treat heart failure come in all shapes, sizes, and colors.




³⁸ Andrea Park, *Entresto puts Novartis at top of docs' ranking of heart disease drug makers, with Pfizer close behind*, Fierce Pharma (May 7, 2024, 4:30 PM), <https://www.fiercepharma.com/marketing/entresto-puts-novartis-top-docs-ranking-heart-disease-drugmakers-pfizer-close-behind> (last visited Jan. 26, 2025).

³⁹ Kyle Blankenship, *Merck, Bayer's trial win for heart failure rival could actually boost Novartis' Entresto*, Fierce Pharma (Nov. 19, 2019, 11:32 AM), <https://www.fiercepharma.com/pharma/merck-bayer-drug-s-trial-win-for-entresto-competitor-could-actually-be-a-boon-for-novartis> (last visited Jan. 26, 2025).

⁴⁰ Kyle Blankenship, *Merck, Bayer's trial win for heart failure rival could actually boost Novartis' Entresto*, Fierce Pharma (Nov. 19, 2019, 11:32 AM), <https://www.fiercepharma.com/pharma/merck-bayer-drug-s-trial-win-for-entresto-competitor-could-actually-be-a-boon-for-novartis> (last visited Jan. 26, 2025); Angus Liu, *Can Merck and Bayer's newly approved Verquvo stand out in an ever-more-competitive heart failure field?*, Fierce Pharma (Jan. 20, 2021 8:10 AM), <https://www.fiercepharma.com/pharma/merck-bayer-win-fda-nod-for-verquvo-even-more-competitive-heart-failure-field> (last visited Jan. 26, 2025).

85. The distinctiveness of the ENTRESTO® Trade Dresses is bolstered by the ENTRESTO® tablets' uniqueness among these other tablets.





86. The variety of shapes, sizes, and colors of competitive tablets demonstrates that the shapes, sizes, and colors of the ENTRESTO® Trade Dresses serve no functional purpose other than source-identification.

Name	Image
FARXIGA®	 ⁴¹
LASIX®	 ⁴²
VASOTEC®	 ⁴³

⁴¹ Farxiga, Drugs.com, <https://www.drugs.com/farxiga.html> (last updated Sept. 2, 2024) (last visited Jan. 26, 2025).

⁴² Lasix, Drugs.com, <https://www.drugs.com/lasix.html> (last updated on Apr. 4, 2023) (last visited Jan. 26, 2025).

⁴³ Vasotec, Drugs.com, <https://www.drugs.com/vasotec.html> (last updated Mar. 1, 2024) (last visited Jan. 26, 2025).


Name	Image
VERQUVO®	 <p>44</p>
COREG®	 <p>45</p>
JARDIANCE®	 <p>46</p>
Valsartan	 <p>47</p>

⁴⁴ Verquvo, Amazon Pharmacy, <https://pharmacy.amazon.com/dp/B09KWJ3X15?> (last visited Jan. 26, 2025).

⁴⁵ Coreg, <https://coreg.com/> (last visited Jan. 26, 2025).

⁴⁶ Jardiance, Drugs.com, <https://www.drugs.com/imprints/s-10-logo-22340.html> (last visited Jan. 26, 2025).

⁴⁷ Valsartan, Drugs.com, <https://www.drugs.com/imprints/hh-342-23594.html> (last updated July 23, 2024) (last visited Jan. 30, 2025).

Name	Image
PRINIVIL®	 48
LOSARTAN®	 49

87. These other heart failure treatments show that colors and shapes serve no functional purpose for tablets like ENTRESTO®.

MSN'S COPYING OF THE ENTRESTO® TRADE DRESSES

88. MSN Labs and its affiliates, MSN Pharma and Novadoz Pharma, manufacture, distribute, and sell generic versions of pharmaceuticals in the United States.

89. On information and belief, MSN intends to imminently launch a sacubitril / valsartan generic drug that is nearly identical in appearance to ENTRESTO®, as soon as an injunction in place in a separate patent appeal pending before the Federal Circuit is lifted. That injunction continues only until the Federal Circuit's mandate in the patent appeal issues, which could happen at any time. MSN's counsel has expressly communicated to Novartis's counsel that MSN will seek to launch the MSN Drug in the window between the issuance of the Federal Circuit's mandate, and the Delaware District Court's further orders once the case is returned after appeal.

⁴⁸ Prinivil, Dugs.com, <https://www.drugs.com/imprints/msd-106-prinivil-193.html> (last visited Jan. 26, 2025).







⁴⁹ Losartan, Drugs.com, <https://www.drugs.com/imprints/e-46-16422.html> (last visited Jan. 26, 2025).

90. On information and belief, the MSN Drug will be offered in three doses that come in shapes, sizes, and colors that mimic those of the ENTRESTO® Trade Dresses.

91. The MSN Drug's label describes the colors of its 24/26 mg, 49/51 mg, and 97/103 mg doses as "[p]urple," "[l]ight yellow," and "[l]ight pink," respectively.⁵⁰ The ENTRESTO® label similarly describes its 24/26 mg, 49/51 mg, and 97/103 mg doses as "violet white," "pale yellow," and "light pink," respectively.

92. The MSN Drug's label further indicates that each tablet will be oval shaped, that the 24/26 mg tablet will be 10mm, the 49/51 mg tablet will be 13mm, and the 97/103 mg tablet will be 15mm.⁵¹ These sizes and shapes almost identically mirror those of the ENTRESTO® Trade Dresses.

93. The images below provide a visual comparison of the ENTRESTO® tablets (top row of the chart) to MSN's tablets (bottom row of the chart).

Image of ENTRESTO® Tablet			
Image of MSN's Tablet⁵²			
Dosage	24/26 mg	49/51 mg	97/103 mg

94. Further, MSN intends to offer its generic with labels directly copying the magenta and blue colors on the respective labels for the Low Starting Dose Trade Dress and

⁵⁰ SACUBITRIL AND VALSARTAN tablet, DailyMed, National Library of Medicine, <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=44db8114-622e-41f6-96a1-447d47b0267c> (last visited Jan. 26, 2025).

⁵¹ *Id.*

⁵² Ex. 2045, *Novartis Pharms. Corp. v. MSN Pharms. Inc.*, No. 1:22-cv-01395 (D. Del. Aug. 8, 2024), ECF No. 263-3 at p. 9.

Recommended Starting Dose Trade Dress, as depicted below (compare MSN labels depicted on top and Novartis's ENTRESTO® labels depicted below).⁵³



⁵³ SACUBITRIL AND VALSARTAN tablet, DailyMed, National Library of Medicine, <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=44db8114-622e-41f6-96a1-447d47b0267c> (last visited Jan. 26, 2025)



MSN'S OFFERING OF THE MSN DRUG WITH THE NOVADOZ BRAND
WILL COMPOUND CONFUSION

95. Upon information and belief, these nearly identical tablets will be manufactured by MSN Labs and distributed by MSN's affiliate Novadoz Pharma, as reflected in the above label images for MSN's Drug. Novadoz Pharma sells generic pharmaceuticals in the United States under the NOVADOZ brand name.

96. Novadoz Pharma has been using the NOVADOZ name to market and sell MSN's generic pharmaceuticals in the United States since 2018.⁵⁴ Although Novartis had previously been concerned about Defendants' uses of NOVADOZ—and raised those concerns for Novadoz Pharma—Novartis did not take enforcement actions based on the facts at that time.

97. Prior to the MSN Drug, Novadoz Pharma has not used the NOVADOZ name in connection with a generic version of a Novartis drug, that copies the protectable trade dress of that Novartis drug—a context in which consumer confusion stemming from use of Novartis's protectable trade dress and the confusingly similar NOVADOZ name is likely to compound.

⁵⁴ *MSN Labs/Novadoz Pharmaceuticals Early Success Continues With FDA Approval Of Generic Abiraterone*, PR Newswire (July 15, 2019), <https://www.prnewswire.com/news-releases/msn-labsnovadoz-pharmaceuticals-early-success-continues-with-fda-approval-of-generic-abiraterone-300884813.html> (last visited Jan. 26, 2025).

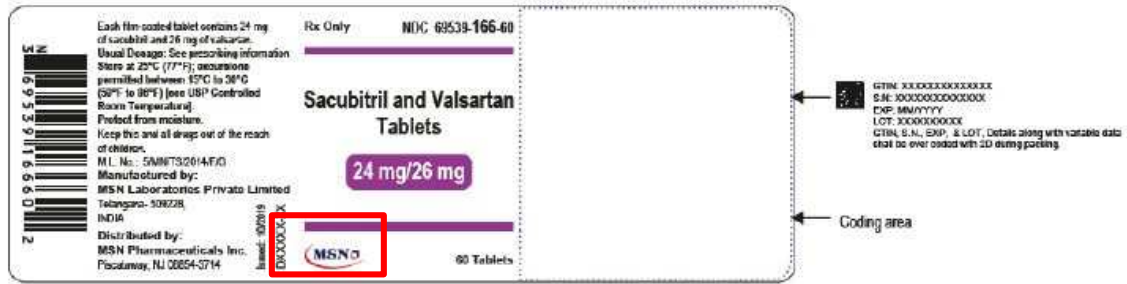
98. As of last week, Novartis now has reason to believe that MSN will use the NOVADOZ name to distribute the MSN Drug on consumer-facing materials, including the MSN Drug's label and package insert:

- a. On January 16, 2025, Novartis discovered that the FDA's Drug Database was updated to reflect that Novadoz Pharma would be the "labeler" of the MSN Drug.⁵⁵
- b. In addition, on January 20, 2025, Novartis discovered a new package insert and package label on the National Library of Medicine's DailyMed database for MSN's Drug showing that the NOVADOZ mark would be used on the insert and label (depicted below). Together, the updated FDA Drug Database and the new label and package insert demonstrate that MSN intends to distribute the MSN Drug in connection with consumer-facing materials prominently displaying the NOVADOZ name.



⁵⁵ Sacubitril and Valsartan, Drug Database, Food & Drug Admin, https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=NONPROPRIETARYNAME&type=Sacubitril+and+Valsartan (last visited Jan. 26, 2025).

99. Prior to these events, Novartis had hoped that MSN intended to avoid confusion by marketing the drug only under the MSN brand because the label it initially submitted to the FDA, shown below, included only the MSN logo:



100. Novadoz Pharma's sale of the MSN Drug under the NOVADOZ name will heighten confusion regarding the source of the MSN Drug because the NOVADOZ name is confusingly similar to Novartis's famous NOVARTIS Trademark, particularly due to its invocation of both the **NOVARTIS** and **SANDOZ** marks.

101. Patients and HCPs are likely to see NOVADOZ branding in connection with the MSN Drug on its packaging or when searching for information about the pharmaceutical online.

102. For example, Novadoz Pharma maintains a public list of its generics, under a section of its website entitled "Products." The list includes the name, image, and description of each product, as well as details such as strength, FDA rating, and therapeutic category; identification of the brand equivalent; and links to prescribing information (the FDA-approved information on the drug, available through the National Library of Medicine's DailyMed database). The top of the webpage not only includes prominent uses of the NOVADOZ name, but also an option for HCPs to "Contact Sales," depicted one the next page.


NOVADOZ[®]
VALUE IN EVERY DOSE

About Us Products Business Development News Generic RX Links Distributors Contact Us Careers [Go To MSN Labs](#)

Home » Products

Products

[Contact Sales](#)




Search here...

[Product-Catalogue](#)

Sort By:

[All](#) A B C D E F G H I J K L M N O P Q R S T U V X Y Z



ABIRATERONE ACETATE TABLETS
 Strength: **250mg** **500mg**
 Description: **White To Off-White, Oval Shaped Tablets .**
 FDA Rating: **AB**
 Imprint Code: **"ABR" / "250"**
 Strength: **250mg**
 Brand Equivalent: **ZYTIGA[®]**
 Therapeutic Category: **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**
 Pack Size: **Bottle Of 120'S**
 Bottle GTIN: **00372205030923**
 Case GTIN: **30372205030924**
 Pallet GTIN: **50372205030928**
 NDC: **72205-004-05, 72205-084-92**

[Prescribing Information](#) [HDA Sheet](#) [SDS Sheet](#) [FAQ's](#)

103. Because the NOVADOZ mark incorporates half of each of the NOVARTIS and SANDOZ marks, consumers are likely to mistakenly believe that NOVADOZ is a generic manufacturer of sacubitril/valsartan combination tablets produced by Novartis, or alternatively, that Novartis is somehow affiliated with or sponsoring MSN's product through Novartis's longstanding relationship with Sandoz.

104. It is the context of Novartis's and Sandoz's decades of work together in the generics space (described in more detail in Paragraphs 41-51 above), that makes MSN's conduct so egregious. Consumers—and particularly HCPs—are primed to believe that Novartis and Sandoz operate as a unit in the generics market. Accordingly, confusion stemming from a combination of the NOVARTIS and SANDOZ marks in connection with a third-party drug is highly likely.

105. MSN's use of NOVADOZ is confusingly similar to the NOVARTIS mark such that consumers are, at first blush, likely to believe it is a use of the NOVARTIS mark or, alternatively, that Novartis and Sandoz have collaborated on a new generic sacubitril/valsartan tablet to substitute for ENTRESTO®. This is particularly true given that, on information and belief, the MSN Drug is nearly identical in appearance to ENTRESTO®, and, to this day, Sandoz still sells Novartis products and products with both the NOVARTIS and SANDOZ brand names are still available for purchase.

THE CONFUSION ARISING FROM MSN'S CONDUCT WILL LEAD TO HARM TO ENTRESTO®'S AND NOVARTIS'S REPUTATIONS AND ASSOCIATED GOODWILL

106. Consumers who receive the MSN Drug are likely to be confused into believing that the MSN Drug is, instead, ENTRESTO® or a Novartis-authorized generic, based on the nearly identical appearance of the products, as well as MSN's confusingly similar uses of the NOVADOZ name.

107. As a result, confused consumers will attribute any issues with the MSN Drug, such as failure to function, negative side effects, or manufacturing issues with the drug like contamination, with ENTRESTO® and its manufacturer Novartis.

108. This attribution of negative patient experiences to ENTRESTO® and Novartis, will harm Novartis's stellar reputation as a trusted provider of high-quality medicines, as well as

ENTRESTO®’s excellent reputation as the top treatment of chronic heart failure and its status as a key driver behind the goodwill of the Novartis brand.

109. MSN’s offering of a confusingly similar product, under the confusingly similar NOVADOZ name, will strip Novartis of the right to control its own reputation and the reputation of its life-changing treatment ENTRESTO®.

THE CONFUSION ARISING FROM MSN’S CONDUCT WILL LEAD TO LOST SALES
FOR NOVARTIS AND WILL DEPRIVE PATIENTS OF THE RIGHT TO MAKE
INFORMED DECISIONS REGARDING THEIR TREATMENT

110. MSN’s conduct is also likely to deprive consumers of the right to make informed decisions concerning their treatment and to lead to lost sales for Novartis.

111. In some states such as Delaware, New Jersey, Illinois, and New Hampshire, pharmacists are permitted to substitute generic drugs with an “AB” rating (which signifies the generic is therapeutically equivalent to the brand name drug) for the brand name drug.

112. The MSN Drug is “AB” rated, such that pharmacists in some states can substitute prescriptions for ENTRESTO® with the MSN Drug, unless the prescribing HCP instructs the pharmacist to dispense the medication as written or indicates that the brand is medically necessary.

113. Patients also have the option to instruct their physicians that they would prefer to receive a branded drug, rather than a generic alternative, and prompt their HCPs to write prescriptions for ENTRESTO® that should be dispensed as written.

114. Patients are likely to give this instruction where the brand manufacturer has invested in its product trade dress and trademarks to cultivate patient loyalty to the brand, as Novartis has done with its ENTRESTO® Trade Dresses and NOVARTIS Trademark.

115. However, given the nearly identical appearance of the MSN Drug and ENTRESTO®, patients are unlikely to even realize that they need to request the brand name

drug. Instead, patients will assume they are receiving ENTRESTO®—the only sacubitril/valsartan drug on the market since 2015.

116. The patient confusion MSN is likely to cause will lead to lost sales for Novartis and, importantly, will deprive patients of the right to make important decisions about what treatment they receive.

117. In addition, where a patient receives the generic substitution and realizes it is not produced by Novartis but—based on the nearly identical appearance of the drugs and MSN’s uses of the NOVADOZ name—believes Novartis is affiliated with or has authorized the MSN drug, the patient will be more willing to try the generic sacubitril/valsartan tablets available for treating chronic heart disease. As a result, they will not request that their physicians indicate that pharmacists should not substitute the generic product when filling the patient’s prescriptions. This too will lead to lost sales for Novartis and deprive patients of the right to make an informed decision about their treatment.

118. Further, patients seeking to refill their prescriptions through online pharmacies that display images of the drugs’ pill tablets may inadvertently request a refill of the generic, rather than ENTRESTO®.

THE CONFUSION ARISING FROM MSN’S CONDUCT WILL
HARM CONSUMERS DUE TO DIFFERENT DOSING INSTRUCTIONS FOR CERTAIN
PATIENTS

119. Patient harm is also likely if patients or HCPs confuse the MSN Drug with ENTRESTO® because the MSN Drug does not explain the proper dosage for certain chronic heart failure patients.

120. It is directed that certain patient populations start sacubitril/valsartan combination drugs at half the recommended starting dose to reduce the risk of serious side effects.

121. Patients who are not taking or are on low doses of certain medications known as angiotensin-converting enzyme inhibitors (“ACEi”) and angiotensin II receptor blockers (“ARB”), are one such patient population that may suffer more serious side effects when starting a sacubitril/valsartan combination medication for the first time.

122. Because of these potential side effects, ENTRESTO®’s label directs patients who are not currently taking an ACEi or ARB or are taking a low dose of those drugs to start by taking the Lower Starting Dose rather than the Recommended Starting Dose.

123. This modified dosing regimen instruction on ENTRESTO®’s label is wholly omitted from the MSN Drug’s label.

124. HCPs receiving NOVADOZ-branded materials about the MSN Drug or marketing materials that show that the MSN Drug is nearly identical in appearance to ENTRESTO®, or alternatively reviewing online resources that incorporate images of the respective drugs and the information on their labels, are likely to assume that the MSN Drug is equivalent to Novartis’s product offering. Based on that inaccurate assumption, HCPs may rely on the MSN Drug’s label and entirely miss key dosing instructions provided by ENTRESTO®’s label for these particular patient populations.

125. Patients would also not see the modified dosing regimen instructions on the MSN Drug label after receiving it from the pharmacy, leaving them unaware of potential side effects of taking the larger starting dose.

126. The negative side effects from taking the wrong dose of the MSN Drug would not only harm the patient but also damage the goodwill associated with the ENTRESTO® Trade Dresses, as a patient might believe that the side effects were caused by ENTRESTO®, rather

than the MSN Drug, due to their nearly identical appearance and the widespread consumer recognition of ENTRESTO® as the source of the different doses.

127. Despite its awareness that its label wholly omits these dosing instructions, MSN decided not to differentiate its product in the market and instead intentionally designed its tablets to look just like the ENTRESTO® tablets. MSN's offering of nearly identical tablets under the NOVADOZ name, risks consumer confusion and the resulting harms described above.

COUNT ONE

Trademark Infringement Section 32 of the Lanham Act, 15 U.S.C. § 1114

128. Plaintiffs repeat and reallege each of the allegations above as if fully set forth herein.

129. Plaintiffs own the NOVARTIS Registered Trademarks—which are five United States trademark registrations for the NOVARTIS trademark (Registration Nos. 4,986,124; 2,336,960; 2,997,235; 5,420,583; 6,841,619). Each of these marks is incontestable.

130. The NOVARTIS Registered Trademarks are valid, subsisting, used in commerce and have inherent and acquired distinctiveness.

131. Defendants, without authorization from Novartis, have used and will continue to use the NOVADOZ mark, which is confusingly similar to Novartis's NOVARTIS Registered Trademarks, on consumer-facing materials in commerce—which became apparent on January 20, 2025, when Novartis discovered a new label for the MSN Drug prominently including the NOVADOZ mark.

132. Plaintiffs' use of the NOVARTIS Registered Trademarks predates any use of the NOVADOZ mark by Defendants.

133. Defendants' use of the NOVADOZ mark to market, sell, and/or distribute the MSN Drug is likely to cause confusion, mistake, and deception among consumers as to whether Defendants' MSN Drug originates from, or is affiliated with, sponsored by, or authorized by Novartis, which markets and sells a very similar drug using its NOVARTIS Registered Trademarks.

134. Defendants' acts constitute trademark infringement of the NOVARTIS Registered Trademarks in violation of Section 32 of the Lanham Act (15 U.S.C. § 1114).

135. As a direct and proximate result of Defendants' use of the confusingly similar NOVADOZ mark, Plaintiffs are likely to suffer irreparable injury to the reputation of Novartis, as well as to the goodwill developed by Novartis for its pharmaceuticals and the NOVARTIS Registered Trademarks. Money cannot compensate these injuries.

136. As a direct and proximate result of Defendants' use of the confusingly similar NOVADOZ mark, Plaintiffs are likely to suffer economic injury through lost sales and price erosion of ENTRESTO® and loss of share in the heart failure medication market. The extent of this harm cannot be ascertained at this time.

137. Defendants' use of the NOVADOZ mark in connection with the MSN Drug is intentional, willful, and in bad faith, evinced by the fact that Defendants—with full knowledge of Plaintiffs' rights in the NOVARTIS Registered Trademarks and concerns regarding the likelihood of confusion stemming from uses of the combination of the Novartis and Sandoz names—knowingly adopted a mark confusingly similar to the NOVARTIS Registered Trademarks to be used on products imitating the ENTRESTO® Trade Dresses in a deceptive manner to pass off their MSN Drug as ENTRESTO®. Defendants' bad faith is further evinced

by the fact that it adopted label colors for its 24/26 mg and 49 /51 mg doses nearly identical to those Novartis uses for the same doses of ENTRESTO®.

138. By reason of the foregoing, Plaintiffs are entitled to injunctive relief against Defendants, restraining Defendants from further acts of infringement of the NOVARTIS Registered Trademarks and, after trial, recovery of any damages (to the extent calculable) proven to have been caused by reason of Defendants' aforesaid acts.

COUNT TWO

False Designation of Origin Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)

139. Plaintiffs repeat and reallege each of the allegations above as if fully set forth herein.

140. Plaintiffs' NOVARTIS Trademark is valid, used in commerce in the United States, and has inherent and acquired distinctiveness.

141. Defendants, without authorization from Novartis, have used and will continue to use the NOVADOZ mark, which is confusingly similar to the NOVARTIS Trademark, on consumer-facing materials in commerce—which became apparent on January 20, 2025, when Novartis discovered a new label for the MSN Drug prominently including the NOVADOZ mark.

142. Plaintiffs' use of the NOVARTIS Trademark predates any use of the NOVADOZ mark by Defendants.

143. Defendants willfully adopted the NOVADOZ mark, with full knowledge of Plaintiffs' rights in the NOVARTIS Trademark and concerns regarding the likelihood of confusion stemming from uses of the combination of the Novartis and Sandoz names.

144. Defendants' use of the NOVADOZ mark to market, sell, and/or distribute the MSN Drug is likely to cause confusion, mistake, and deception among consumers as to whether

Defendants' MSN Drug originates from, or is affiliated with, sponsored by, or authorized by Novartis, which markets and sells a very similar drug using its NOVARTIS Trademark.

145. Defendants' acts constitute trademark infringement of the NOVARTIS Trademark in violation of Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)(1)).

146. As a direct and proximate result of Defendants' use of the confusingly similar NOVADOZ mark, Plaintiffs are likely to suffer irreparable injury to the reputation of Novartis, as well as to the goodwill developed by Novartis for its pharmaceuticals and the NOVARTIS Trademark. The extent of this harm cannot be ascertained at this time.

147. As a direct and proximate result of Defendants' use of the confusingly similar NOVADOZ mark, Plaintiffs are likely to suffer economic injury through lost sales and price erosion of ENTRESTO® and loss of share in the heart failure medication market. The extent of this harm cannot be ascertained at this time.

148. Defendants' use of the NOVADOZ mark is intentional, willful, and in bad faith, evinced by the fact that Defendants—with full knowledge of Plaintiffs' rights in the NOVARTIS Trademark and concerns regarding the likelihood of confusion stemming from uses of the combination of the Novartis and Sandoz names—knowingly adopted a mark confusingly similar to the NOVARTIS Trademark to be used on products imitating the ENTRESTO® Trade Dresses, in a deceptive manner to pass off its MSN Drug as ENTRESTO®. Defendants' bad faith is further evinced by the fact that it adopted label colors for its 24/26 mg and 49 /51 mg doses nearly identical to those Novartis uses for the same doses of ENTRESTO®.

149. By reason of the foregoing, Plaintiffs are entitled to injunctive relief against Defendants, restraining Defendants from further acts of infringement of the NOVARTIS

Trademark and, after trial, recovery of any damages (to the extent calculable) proven to have been caused by reason of Defendants' aforesaid acts.

COUNT THREE

**Trade Dress Infringement
Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)**

150. Plaintiffs repeat and reallege each of the allegations above as if fully set forth herein.

151. Plaintiffs own valid trade dress rights in the ENTRESTO® Trade Dresses.

152. The ENTRESTO® Trade Dresses are used in commerce in the United States.

153. The ENTRESTO® Trade Dresses are non-functional and have acquired secondary meaning in the marketplace.

154. Defendants, without authorization from Plaintiffs, have used and will continue to use trade dresses confusingly similar to the ENTRESTO® Trade Dresses in commerce (including through the manufacturing and importation of the MSN Drug, as well as preparations for the imminent launch of the MSN Drug).

155. Defendants' use of the ENTRESTO® Trade Dresses is likely to cause confusion, mistake, and deception among consumers as to whether Defendants' MSN Drug is ENTRESTO®, or otherwise sponsored or authorized by Novartis.

156. Defendants' acts constitute trade dress infringement in violation of Section 43(a) of the Lanham Act (15 U.S.C. § 1125(a)).

157. As a direct and proximate result of Defendants' use of confusingly similar trade dress, Plaintiffs are likely to suffer irreparable injury to the reputation of Novartis, as well as to the goodwill developed by Novartis for ENTRESTO® and the ENTRESTO® Trade Dresses. The extent of this harm cannot be ascertained at this time.

158. As a direct and proximate result of Defendants' use of confusingly similar trade dress, Plaintiffs are likely to suffer economic injury through lost sales and price erosion of ENTRESTO® and loss of share in the heart failure medication market. The extent of this harm cannot be ascertained at this time.

159. Defendants' use of confusingly similar trade dress is intentional, willful, and in bad faith, evinced by the fact that Defendants knowingly adopted a trade dress blatantly copying the ENTRESTO® Trade Dresses, in a deceptive manner to pass off its MSN Drug as ENTRESTO®.

160. By reason of the foregoing, Plaintiffs are entitled to injunctive relief against Defendants, restraining Defendants from further acts of infringement of the ENTRESTO® Trade Dresses and, after trial, recovery of any damages (to the extent calculable) proven to have been caused by reason of Defendants' aforesaid acts.

COUNT FOUR

Trademark Infringement N.J. S.A. § 56:4-1 et seq.

161. Plaintiffs repeat and reallege each of the allegations above as if fully set forth herein.

162. Plaintiffs own five United States trademark registrations for the NOVARTIS Trademark (Registration Nos. 4,986,124; 2,336,960; 2,997,235; 5,420,583; 6,841,619). Each of these marks is incontestable.

163. Plaintiffs' NOVARTIS Trademark is valid, used in commerce in the United States, and has inherent and acquired distinctiveness.

164. Defendants, without authorization from Novartis, have used and will continue to use the NOVADOZ mark, which is confusingly similar to the NOVARTIS Trademark, on

consumer-facing materials in commerce—which became apparent on January 20, 2025, when Novartis discovered a new label for the MSN Drug prominently including the NOVADOZ mark.

165. Plaintiffs’ use of the NOVARTIS Trademark predates any use of the NOVADOZ mark by Defendants.

166. Defendants’ use of the NOVADOZ mark to market, sell, and/or distribute the MSN Drug is likely to continue to cause confusion, mistake, and deception among consumers as to whether Defendants’ MSN Drug originates from, or is affiliated with, sponsored by, or authorized by Novartis, which markets and sells a very similar drug using its NOVARTIS Trademark.

167. Defendants’ acts constitute trademark infringement in violation of N.J.S.A. § 56:4-1.

168. As a direct and proximate result of Defendants’ use of the confusingly similar NOVADOZ mark, Plaintiffs are likely to suffer irreparable injury to the reputation of Novartis, as well as to the goodwill developed by Novartis for its pharmaceuticals and the NOVARTIS Trademark. The extent of this harm cannot be ascertained at this time.

169. As a direct and proximate result of Defendants’ use of the confusingly similar NOVADOZ mark, Plaintiffs are likely to suffer economic injury through lost sales and price erosion of ENTRESTO® and loss of share in the heart failure medication market. The extent of this harm cannot be ascertained at this time.

170. Defendants’ use of the NOVADOZ mark is intentional, willful, and in bad faith, evinced by the fact that Defendants knowingly adopted a mark confusingly similar to the NOVARTIS Trademark to be used on products imitating the ENTRESTO® Trade Dresses in a

deceptive manner to pass off its MSN Drug as ENTRESTO®. Defendants' bad faith is further evinced by the fact that it adopted label colors for its 24/26 mg and 49 /51 mg doses nearly identical to those Novartis uses for the same doses of ENTRESTO®.

171. By reason of the foregoing, Plaintiffs are entitled to injunctive relief against Defendants, restraining Defendants from further infringement of the NOVARTIS Trademark, and all damages, whether direct or indirect, for the misappropriation of Plaintiffs' NOVARTIS Trademark, which damages are subject to trebling.

COUNT FIVE

Trade Dress Infringement N.J. S.A. § 56:4-1 et seq.

172. Plaintiffs repeat and reallege each of the allegations above as if fully set forth herein.

173. Plaintiffs own valid trade dress rights in the ENTRESTO® Trade Dresses.

174. The ENTRESTO® Trade Dresses are used in commerce.

175. The ENTRESTO® Trade Dresses are non-functional and have acquired secondary meaning in the marketplace.

176. Defendants, without authorization from Plaintiffs, have used and will continue to use trade dresses confusingly similar to the ENTRESTO® Trade Dresses in commerce (including through the manufacturing and importation of the MSN Drug, as well as preparations for the imminent launch of the MSN Drug).

177. Defendants' use of the ENTRESTO® Trade Dresses is likely to cause confusion, mistake, and deception among consumers as to whether Defendants' MSN Drug is Novartis's trusted ENTRESTO® drug, or otherwise sponsored or authorized by Novartis.

178. Defendants' acts constitute trademark infringement in violation of N.J.S.A. § 56:4-1.

179. As a direct and proximate result of Defendants' use of confusingly similar trade dress, Plaintiffs are likely to suffer irreparable injury to the reputation of Novartis, as well as to the goodwill developed by Novartis for ENTRESTO® and the ENTRESTO® Trade Dresses. The extent of this harm cannot be ascertained at this time.

180. As a direct and proximate result of Defendants' use of confusingly similar trade dress, Plaintiffs are likely to suffer economic injury through lost sales and price erosion of ENTRESTO® and loss of share in the heart failure medication market. The extent of this harm cannot be ascertained at this time.

181. Defendants' use of confusingly similar trade dress has been intentional and was done with knowledge of the considerable reputation, goodwill, and fame associated with the ENTRESTO® Trade Dresses.

182. By reason of the foregoing, Plaintiff is entitled to injunctive relief against Defendants, restraining Defendants from further acts of infringement of the ENTRESTO® Trade Dresses and, after trial, recovery of any damages (to the extent calculable) proven to have been caused by reason of Defendants' aforesaid acts.

183. By reason of the foregoing, Plaintiffs are entitled to injunctive relief against Defendants, restraining Defendants from further infringement of the ENTRESTO® Trade Dresses, and all damages, whether direct or indirect, for the misappropriation of Plaintiffs' ENTRESTO® Trade Dresses, which damages are subject to trebling.

COUNT SIX

Common Law Unfair Competition and Trademark Infringement

184. Plaintiffs repeat and reallege each of the allegations above as if fully set forth herein.

185. Plaintiffs own five United States trademark registrations for the NOVARTIS Trademark (Registration Nos. 4,986,124; 2,336,960; 2,997,235; 5,420,583; 6,841,619). Each of these marks is incontestable.

186. The NOVARTIS Trademark is valid, subsisting, used in commerce and has inherent and acquired distinctiveness.

187. Defendants, without authorization from Novartis, have used and will continue to use the NOVADOZ mark, which is confusingly similar to Novartis's NOVARTIS Trademark, on consumer-facing materials in commerce—which became apparent on January 20, 2025, when Novartis discovered a new label for the MSN Drug prominently including the NOVADOZ mark.

188. Plaintiffs' use of the NOVARTIS Trademark predates any use of the NOVADOZ mark by Defendants.

189. Defendants' use of the NOVADOZ mark to market, sell, and/or distribute the MSN Drug is likely to continue to cause confusion, mistake, and deception among consumers as to whether Defendants' MSN Drug originates from, or is affiliated with, sponsored by, or authorized by Novartis, which markets and sells a very similar drug using its NOVARTIS Trademark.

190. The foregoing acts of Defendants constitute unfair competition and trademark infringement in violation of New Jersey common law.

191. As a direct and proximate result of Defendants' use of the confusingly similar NOVADOZ mark, Plaintiffs are likely to suffer irreparable injury to the reputation of Novartis,

as well as to the goodwill developed by Novartis for its pharmaceuticals and the NOVARTIS Trademark. Money cannot compensate these injuries.

192. As a direct and proximate result of Defendants' use of the confusingly similar NOVADOZ mark, Plaintiffs are likely to suffer economic injury through lost sales and price erosion of ENTRESTO® and loss of share in the heart failure medication market. The extent of this harm cannot be ascertained at this time.

193. Defendants' use of the NOVADOZ mark is intentional, willful, and in bad faith, evinced by the fact that Defendants knowingly adopted a mark confusingly similar to the NOVARTIS Trademark to be used on products imitating the ENTRESTO® Trade Dresses in a deceptive manner to pass off its MSN Drug as ENTRESTO®. Defendants' bad faith is further evinced by the fact that it adopted label colors for its 24/26 mg and 49 /51 mg doses nearly identical to those Novartis uses for the same doses of ENTRESTO®.

194. By reason of the foregoing, Plaintiffs are entitled to injunctive relief against Defendants, restraining Defendants from further infringement of the NOVARTIS Trademark, and all damages, whether direct or indirect, for the misappropriation of Plaintiffs' NOVARTIS Trademark.

COUNT SEVEN

Common Law Unfair Competition and Trademark Infringement

195. Plaintiffs repeat and reallege each of the allegations above as if fully set forth herein.

196. Plaintiffs own valid trade dress rights in the ENTRESTO® Trade Dresses.

197. The ENTRESTO® Trade Dresses are used in commerce.

198. The ENTRESTO® Trade Dresses are non-functional and have acquired secondary meaning in the marketplace.

199. Defendants, without authorization from Plaintiffs, have used and will continue to use trade dresses confusingly similar to the ENTRESTO® Trade Dresses in commerce (including through the manufacturing and importation of the MSN Drug, as well as preparations for the imminent launch of the MSN Drug).

200. Defendants' use of the ENTRESTO® Trade Dresses is likely to cause confusion, mistake, and deception among consumers as to whether Defendants' MSN Drug is Novartis's trusted ENTRESTO® drug.

201. The foregoing acts of Defendants constitute unfair competition and trademark infringement in violation of New Jersey common law.

202. As a direct and proximate result of Defendants' use of confusingly similar trade dress, Plaintiffs are likely to suffer irreparable injury to the reputation of Novartis, as well as to the goodwill developed by Novartis for ENTRESTO® and the ENTRESTO® Trade Dresses. Money cannot compensate these injuries.

203. As a direct and proximate result of Defendants' use of confusingly similar trade dress, Plaintiffs are likely to suffer economic injury through lost sales and price erosion of ENTRESTO® and loss of share in the heart failure medication market. The extent of this harm cannot be ascertained at this time.

204. Defendants' use of confusingly similar trade dress has been intentional and was done with knowledge of the considerable reputation and goodwill associated with the ENTRESTO® Trade Dresses.

205. By reason of the foregoing, Plaintiffs are entitled to injunctive relief against Defendants, restraining Defendants from further acts of infringement of the ENTRESTO® Trade

Dresses and, after trial, recovery of any damages (to the extent calculable) proven to have been caused by reason of Defendants' aforesaid acts.

COUNT EIGHT

Declaratory Judgment

206. Plaintiffs repeat and reallege each of the allegations above as if fully set forth herein.

207. There is a justiciable case or controversy between the parties as to Defendants' trade dress infringement, trademark infringement, and unfair competition as alleged in Counts One through Seven above, including because Defendants are imminently prepared to distribute and market the MSN Drug to U.S. consumers using (i) trade dresses that are confusingly similar to the ENTRESTO® Trade Dresses and (ii) the NOVADOZ mark, which is confusingly similar to the NOVARTIS Trademark.

208. Plaintiff is the owner of the valid NOVARTIS Trademarks and the valid ENTRESTO® Trade Dresses.

209. The trade dresses of the MSN Drug tablets are confusingly similar to the ENTRESTO® Trade Dresses, and uses of these trade dresses is likely to cause confusion, mistake, and deception among consumers as to whether Defendants' MSN Drug is ENTRESTO®, or otherwise sponsored or authorized by Novartis.

210. Defendants' use of the NOVADOZ mark to market, sell, and/or distribute the MSN Drug is likely to cause confusion, mistake, and deception among consumers as to whether Defendants' MSN Drug originates from, or is affiliated with, sponsored by, or authorized by Novartis, which markets and sells a very similar drug using its NOVARTIS Trademark.

211. This case is appropriate for a declaratory judgment under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

212. Plaintiffs are entitled to a judicial declaration that Defendants' current and imminent use of trade dresses confusingly similar to the ENTRESTO® Trade Dresses and use of the NOVADOZ mark in connection with tablets using those trade dresses is likely to cause confusion, mistake, and deception among consumers as to whether Defendants' MSN Drug is Novartis's ENTRESTO® drug, or otherwise sponsored or authorized by Novartis in violation of Section 32 of the Lanham Act, 15 U.S.C. § 1114; Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); N.J.S.A. § 56:4-1; and the common law of the State of New Jersey.

PRAYER FOR RELIEF

Plaintiffs respectfully request:

A. Judgment that Defendants have infringed the NOVARTIS Registered Trademarks in violation of Section 32 of the Lanham Act, 15 U.S.C. § 1114.

B. Judgment that Defendants have infringed the NOVARTIS Trademark in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

C. Judgment that Defendants have infringed the ENTRESTO® Trade Dresses in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1).

D. Judgment that Defendants have engaged in unfair competition under New Jersey Law, N.J.S.A. § 56:4-1;

E. Judgment that Defendants have infringed the ENTRESTO® Trade Dresses under the common law of the State of New Jersey;

F. Judgment that Defendants have infringed the NOVARTIS Trademark under the common law of the State of New Jersey;

G. Judgment that Defendants have engaged in unfair competition under the common law of the State of New Jersey;

H. A declaration that the MSN Generic and use of the NOVADOZ mark in connection with the MSN Generic is likely to cause confusion, mistake, and deception among consumers as to whether Defendants' MSN Drug is Novartis's ENTRESTO® drug, or otherwise sponsored or authorized by Novartis in violation of Section 32 of the Lanham Act, 15 U.S.C. § 1114; Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); N.J.S.A. § 56:4-1; and the common law of the State of New Jersey;

I. A preliminary and permanent injunction enjoining and restraining Defendants and all those acting in concert or participation with Defendants from offering pharmaceuticals that infringe the ENTRESTO® Trade Dresses;

J. A preliminary and permanent injunction enjoining and restraining Defendants from distributing a generic sacubitril/valsartan drug, confusingly similar in appearance to Novartis's ENTRESTO® Trade Dresses (*e.g.*, including the tablets depicted in MSN's ANDA App. #213748), and using the NOVADOZ brand in connection with the sale or offering for sale of that product;

K. An award of Plaintiffs' costs of litigation and attorneys' fees to the full extent provided for under the law, including by Section 43 of the Lanham Act, 15 U.S.C. § 1125; and

L. Such other and further relief as the Court deems just and proper.

Dated: January 30, 2025
New York, New York

DEBEVOISE & PLIMPTON LLP

By: /s/ Megan K. Bannigan
Megan K. Bannigan (mkbannigan@debevoise.com)
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard

New York, New York 10001

(212) 909-6000

*Attorneys for Plaintiffs Novartis AG and Novartis
Pharmaceuticals Corporation*

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation, by and through their attorneys, certify that insofar as the matter in controversy is infringement of the ENTRESTO® trade dresses and NOVARTIS trademark, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. However, insofar as the matter in controversy is MSN's launch of a generic version of ENTRESTO®, the following actions pertaining to patent infringement and the FDA's approval of MSN's drug are pending:

- *Novartis Pharms. Corp. v. MSN Pharms. Inc.*, No. 22 CV 01395 (D. Del.).

Plaintiff is Novartis Pharmaceuticals Corporation. Defendants are MSN Pharmaceuticals Inc., MSN Laboratories Private Ltd., MSN Life Sciences Private Ltd., Nanjing Noratech Pharmaceutical Co. Ltd., and Gerbera Therapeutics Inc.
- *Novartis Pharms. Corp. v. MSN Pharms. Inc.*, No. 25 CV 00081 (D. Del.).

Plaintiff is Novartis Pharmaceuticals Corporation. Defendants are MSN Pharmaceuticals Inc., MSN Laboratories Private Ltd., MSN Life Sciences Private Ltd., and Novadoz Pharmaceuticals, LLC.
- *Novartis Pharms. Corp. v. MSN Pharms. Inc.*, Appeal No. 24-2211 (Fed. Cir.).

Plaintiff-Appellant is Novartis Pharmaceuticals Corporation. Defendant-Appellees are MSN Pharmaceuticals Inc., MSN Laboratories Private Ltd., and MSN Life Sciences Private Ltd.
- *Novartis Pharms. Corp. v. Torrent Pharma Inc.*, Appeal No. 23-2218 (Fed. Cir.).

Plaintiff-Appellant is Novartis Pharmaceuticals Corporation.

Defendant-Appellees are MSN Pharmaceuticals Inc., MSN Laboratories Private Ltd., and MSN Life Sciences Private Ltd.

- *Novartis Pharms. Corp. v. Becerra et al.*, Appeal No. 24-5186 (D.C. Cir.).

Plaintiff-Appellant is Novartis Pharmaceuticals Corporation. Defendant-Appellees are Robert McKinnon Califf, M.D., in his official capacity as Commissioner of Food and Drugs, Food and Drug Administration, and Xavier Becerra, in his official capacity as Secretary of Health and Human Services. Intervenor for Defendant-Appellees are MSN Pharmaceuticals Inc. and MSN Laboratories Private Ltd.

Dated: January 30, 2025
New York, New York

DEBEVOISE & PLIMPTON LLP

By: /s/ Megan K. Bannigan
Megan K. Bannigan (mkbannigan@debevoise.com)
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, New York 10001
(212) 909-6000
*Attorneys for Plaintiffs Novartis AG and Novartis
Pharmaceuticals Corporation*

LOCAL CIVIL RULE 201.1 CERTIFICATION

Pursuant to Local Civil Rule 201.1, Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation, by and through their attorneys, certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, inter alia, injunctive relief.

Dated: January 30, 2025
New York, New York

DEBEVOISE & PLIMPTON LLP

By: /s/ Megan K. Bannigan
Megan K. Bannigan (mkbannigan@debevoise.com)
DEBEVOISE & PLIMPTON LLP
66 Hudson Boulevard
New York, New York 10001
(212) 909-6000
*Attorneys for Plaintiffs Novartis AG and Novartis
Pharmaceuticals Corporation*